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THE IMPORTANCE OF ELECTRONIC CONSENT FORMS IN CLINICAL RESEARCH

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I. Introduction

The roots of clinical research can be traced back to ancient times when early civilizations engaged in rudimentary forms of medical experimentation. Over the centuries, the practice evolved from anecdotal observations to more systematic and structured approaches. However, it wasn't until the 20th century that clinical research emerged as a distinct and formalized discipline.

The evolution of clinical research has been marked by significant milestones, including the development of ethical principles and guidelines to protect research participants. One crucial aspect of this evolution is the transformation of consent forms, which serve as a fundamental tool in ensuring that individuals voluntarily and knowingly participate in research studies.

The evolution of consent forms is closely tied to the broader historical context of medical

Abstract: Clinical research, a cornerstone of medical progress, is an intricate and dynamic field aimed at advancing our understanding of diseases, developing innovative treatments, and improving overall healthcare outcomes. The background of clinical research is deeply rooted in the pursuit of knowledge and the desire to enhance medical practices. Historically, clinical research has been driven by the need to address unanswered questions in medicine and to find effective interventions for various health conditions.

ethics. In the aftermath of World War II, revelations about unethical medical experiments conducted by the Nazis prompted the international community to establish ethical standards for human research. The Nuremberg Code, developed in 1947, laid the foundation for informed consent by emphasizing the voluntary and informed nature of participants' consent.^{1, 2}

As clinical research expanded and diversified, so did the complexity of the informed consent process. The traditional approach involved paper consent forms, where participants were provided with written information about the study and asked to sign a document indicating their agreement to participate. While this method served its purpose for many years, it became evident that traditional consent forms had limitations and were not always effective in ensuring true comprehension and voluntary participation.

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The advent of electronic consent forms (econsent) represents a paradigm shift in the way researchers obtain and manage informed consent. This evolution is driven by the rapid advancements in technology and the recognition of the potential benefits that electronic methods can offer to both researchers and participants. Electronic consent forms leverage digital platforms to present information in a more interactive and engaging manner, incorporating multimedia elements such as videos and interactive graphics to enhance participant understanding.

One key advantage of electronic consent forms is their ability to address some of the challenges associated with traditional paper forms. Traditional consent forms were often lengthy, complex, and written in technical language, making it difficult for participants to grasp the essential information. E-consent allows for a more user-friendly and tailored approach, presenting information in a step-bystep manner and allowing participants to navigate through the content at their own pace.

Moreover, the evolution of consent forms aligns with the broader shift toward patientcentered care and a recognition of the importance of participant autonomy. Electronic consent forms empower individuals by providing them with a greater degree of control over the consent process. Participants can review information at their convenience, ask questions in real-time, and electronically sign the consent document, all contributing to a more transparent and participant-friendly experience.

The evolution of consent forms is also intertwined with legal and ethical considerations. The regulatory landscape research has become governing clinical increasingly complex, with stringent requirements to protect participants' rights and ensure the integrity of the research process. Electronic consent forms offer features such as audit trails and version control, which enhance compliance with regulatory standards and provide a transparent record of the consent process.

Informed consent, a cornerstone of ethical research, emphasizes the principle of autonomy, ensuring that individuals have the make decisions about right to their participation in research based on adequate information. The evolution of consent forms reflects a commitment to upholding the principles of informed consent and underscores the importance of respecting participants' autonomy.

As the landscape of clinical research continues to evolve, the role of electronic consent forms becomes even more prominent. These digital tools not only streamline the consent process but also contribute to the overall efficiency and of research studies. effectiveness The integration of electronic consent forms with electronic health records further enhances the seamless flow of information and documentation, reducing the administrative burden on researchers and institutions.^{1,3}

II. Traditional Consent Forms vs. Electronic Consent Forms

A. Challenges with Traditional Paper Forms

The utilization of traditional paper consent forms in clinical research has been a longstanding practice, but it comes with inherent challenges that have prompted the exploration of more efficient alternatives. This section delves into the limitations associated with traditional consent forms, shedding light on the factors that have driven the need for a paradigm shift in the informed consent process.

Complexity and Length:

Traditional paper consent forms are often characterized by complex language and lengthy documents that can be overwhelming for participants. The intricate medical terminology and dense content may impede comprehension, leading to potential misunderstandings about the research study. Limited Interactivity:

Paper consent forms lack interactivity, making it challenging for participants to engage with the information. The static nature of these forms hinders the dynamic exchange of information between researchers and participants, potentially resulting in a less informed decision-making process.

Inconsistency in Delivery:

Researchers may struggle maintain to consistency in the delivery of information when using paper forms. Variability in how information is presented and explained to compromise participants can the standardization of the consent process, introducing potential biases and misunderstandings.

Storage and Retrieval Challenges:

Managing and storing numerous paper consent forms can be cumbersome for research institutions. The manual handling of physical documents increases the risk of errors, loss, or damage, posing challenges in maintaining an organized and accessible record-keeping system.

Limited Accessibility:

Paper forms may present barriers to accessibility for certain populations, including those with visual impairments or individuals who speak languages other than the one in which the form is written. This limitation raises concerns about inclusivity in research participation.⁴

B. Advantages of Electronic Consent Forms

With the advent of technology, electronic consent forms (e-consent) have emerged as a progressive alternative to traditional paperbased methods. This section explores the advantages offered by electronic consent forms, highlighting the transformative impact of digital solutions on the informed consent process in clinical research. Enhanced Participant Understanding:

Electronic consent forms employ multimedia elements such as videos, animations, and interactive graphics to convey information in a more digestible format. This multimedia approach enhances participant understanding by catering to diverse learning styles and providing a more engaging educational experience.

Real-time Interaction and Feedback:

Unlike their static paper counterparts, electronic consent forms facilitate real-time interaction between researchers and participants. Participants can ask questions, seek clarification, and receive immediate feedback, fostering a dynamic and transparent consent process that promotes genuine comprehension.

Tailored and Modular Presentation:

E-consent allows for a modular presentation of information, breaking down complex concepts into smaller, more manageable sections. Participants can navigate through the content at their own pace, ensuring that they fully grasp each aspect before proceeding, thereby promoting a more personalized and tailored approach to the consent process.

Efficient Data Management:

Electronic consent forms streamline the data management process, providing features such as audit trails and version control. These features enhance the accuracy, traceability, and security of the consent process, addressing regulatory requirements and contributing to the overall integrity of the research study.

Integration with Electronic Health Records (EHRs):

The integration of electronic consent forms with EHRs establishes a seamless flow of information between different stages of the research process. This integration not only reduces administrative burdens on researchers but also enhances the continuity and completeness of participant records, fostering a

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more cohesive and efficient research environment.

Improved Accessibility and Inclusivity:

Electronic consent forms can be designed to accommodate diverse needs, including translations for multiple languages and features for accessibility. This inclusivity ensures that a broader range of individuals, including those with disabilities or language barriers, can participate in research studies, promoting a more representative and diverse participant pool.

III. Legal and Ethical Considerations

A. Regulatory Framework

The landscape of clinical research is intricately governed by a comprehensive regulatory framework that outlines the rights and protections afforded to research participants. This section explores the key components of the regulatory framework governing the use of consent forms in clinical research, emphasizing the legal obligations and standards that researchers must adhere to.

International Standards and Guidelines:

Clinical within research operates an international context guided by ethical principles and standards. Notable documents such as the Declaration of Helsinki and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines provide a global framework for ethical conduct in research, emphasizing the importance of informed consent.

National and Regional Regulations:

Each country and region has its own set of regulations governing clinical research. These regulations may include requirements for the content and format of consent forms, procedures for obtaining informed consent, and the establishment of ethical review boards or institutional review boards (IRBs) to oversee research protocols. U.S. Federal Regulations:

In the United States, clinical research is subject to federal regulations, including the Common Rule (45 CFR 46) and the Food and Drug Administration (FDA) regulations. These regulations provide guidelines on informed consent, the composition and functions of IRBs, and the protection of human subjects in research.

European Union Regulations:

The European Union (EU) has established the General Data Protection Regulation (GDPR) and the Clinical Trials Regulation to govern clinical protection and research. data respectively. These regulations emphasize the rights of individuals regarding the use of their and set standards personal data for transparency and accountability in research practices.

Ethics Committee Oversight:

Many regulatory frameworks require the establishment of ethics committees or IRBs to review and approve research protocols. These committees ensure that research is conducted ethically, with a focus on participant welfare, and that informed consent processes meet the necessary ethical standards.⁵

B. Informed Consent and Participant Autonomy

The concept of informed consent lies at the heart of ethical clinical research, emphasizing the importance of transparency, autonomy, and voluntary participation. This subsection explores the ethical considerations surrounding informed consent and the central role it plays in upholding participant autonomy.

Voluntariness and Coercion:

Informed consent must be obtained voluntarily, free from any form of coercion or undue influence. Researchers are obligated to create an environment where participants feel comfortable declining participation without fear of negative consequences.

Comprehension and Disclosure:

An essential aspect of informed consent is the participants' understanding of the information provided. Researchers must disclose relevant details about the study in a clear and understandable manner, ensuring that participants comprehend the purpose, risks, benefits, and alternatives to participation.⁶

Ongoing Informed Consent:

The informed consent process is not a one-time event but rather an ongoing dialogue between researchers and participants. Changes in the research protocol or new information that may impact the participants' decision should be communicated promptly, and their consent should be reaffirmed.

Proxy Consent and Vulnerable Populations:

In certain situations, individuals may lack the capacity to provide informed consent (e.g., minors, those with cognitive impairments). Proxy consent, obtained from legally authorized representatives, is permissible in such cases. Special considerations and additional safeguards are implemented to protect the rights of vulnerable populations.

C. Data Security and Privacy

The collection and management of participant data in clinical research necessitate a strong commitment to data security and privacy protection. This section delves into the legal and ethical considerations surrounding the safeguarding of participant information.⁴

HIPAA Compliance:

In the United States, the Health Insurance Portability and Accountability Act (HIPAA) imposes strict regulations on the protection of participants' health information. Researchers must implement measures to ensure the confidentiality and security of participant data, especially when electronic consent forms are used.

GDPR Compliance:

For research conducted in the European Union or involving EU participants, compliance with the GDPR is essential. The GDPR mandates transparent data processing practices, explicit consent for data processing, and the implementation of security measures to protect personal data.

Data Encryption and Storage:

Electronic consent forms often involve the collection and transmission of sensitive participant data. Encryption technologies and secure storage systems are crucial for protecting the confidentiality and integrity of this information, minimizing the risk of unauthorized access or data breaches.

Participant Data Access and Control:

Participants have the right to control their personal data. Researchers must clearly communicate how participant data will be used, stored, and shared. Providing participants with options to revoke consent or control their data preferences contributes to a participant-centric approach to data security and privacy.

IV. Streamlining the Consent Process

A. Improved Participant Understanding

Efforts to streamline the consent process in clinical research are intrinsically linked to enhancing participant understanding. This section explores strategies and innovations aimed at improving how information is presented to participants, ensuring that they have a comprehensive grasp of the study details.

Multimedia Integration:

Electronic consent forms leverage multimedia elements such as videos, animations, and interactive graphics to convey complex information. This approach caters to diverse learning styles, making the content more accessible and engaging for participants. Visual aids can elucidate key concepts, medical procedures, and potential risks, contributing to a more thorough understanding.

Plain Language and Simplified Content:

Recognizing the potential for confusion in complex medical terminology, researchers

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strive to use plain language in consent forms. Simplified content ensures that participants, regardless of their educational background, can comprehend the essential information. Clear and straightforward language facilitates a more transparent exchange of information, aligning with the principle of informed consent.

Modular Presentation of Information:

Electronic consent forms allow for a modular presentation of information, breaking down the study details into manageable sections. This approach enables participants to navigate through the content at their own pace, ensuring that each component is understood before proceeding. The modular format promotes a more personalized and tailored approach to the consent process, fostering improved participant comprehension.

Assessment of Participant Understanding:

Incorporating interactive quizzes or assessments within electronic consent forms can serve as a valuable tool to gauge participant comprehension. Real-time feedback on their understanding of key concepts allows researchers to identify areas of potential confusion and address participant questions promptly, contributing to a more robust informed consent process.

B. Real-time Feedback and Communication

One of the hallmarks of electronic consent forms is their ability to facilitate real-time feedback and communication between researchers and participants. This subsection explores how this dynamic interaction contributes to the efficiency and effectiveness of the consent process.

Interactive Q&A Sessions:

Electronic consent forms enable participants to ask questions in real-time, fostering an interactive dialogue between researchers and participants. 0&A features allow for clarification on study details, potential risks, procedural aspects, ensuring and that participants can make informed decisions based on accurate information.

Immediate Clarifications and Updates:

Researchers can address participant queries and provide immediate clarifications through electronic communication channels. Additionally, if there are updates or modifications to the study protocol, participants can be promptly informed, maintaining transparency and ensuring ongoing informed consent throughout the research study.

Secure Messaging Systems:

Electronic consent processes can incorporate secure messaging systems to facilitate confidential communication between researchers and participants. This ensures that sensitive information is transmitted securely, meeting data protection and privacy standards while allowing participants to seek clarification or express concerns in a private and secure environment.

Documentation of Communication:

The electronic format enables the documentation of communication exchanges between researchers and participants. This not only provides a record of the informed consent process but also contributes to the transparency and accountability of the research study, meeting regulatory requirements for thorough documentation.

C. Accessibility and Inclusivity

Ensuring that the informed consent process is accessible to diverse populations is a crucial aspect of streamlining the consent process. This section explores how electronic consent forms contribute to accessibility and inclusivity in clinical research.

Multilingual Capabilities:

Electronic consent forms can be designed to accommodate multiple languages, addressing facilitating language barriers and the participation of individuals from diverse linguistic backgrounds. This multilingual capability enhances inclusivity and ensures that participants fully understand the study information in their preferred language.

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Adaptive Design for Accessibility:

Electronic consent forms can incorporate adaptive design elements to enhance accessibility for individuals with disabilities. Features such as text-to-speech functionality, adjustable font sizes, and compatibility with screen readers contribute to a more inclusive consent process, accommodating participants with varying needs.

Remote Participation Options:

The electronic format enables researchers to reach participants in geographically distant locations. Remote participation options, facilitated through electronic consent forms, reduce logistical barriers and enhance accessibility for individuals who may face challenges in physically attending study sites.

User-friendly Interfaces:

Designing user-friendly interfaces is integral to ensuring that electronic consent forms are accessible to individuals with varying levels of technological proficiency. Intuitive navigation, clear instructions, and user-friendly interfaces contribute to a positive user experience, making the consent process more accessible to a broader participant demographic.

V. Enhancing Compliance and Documentation

A. Audit Trail and Version Control

The meticulous documentation of the informed consent process is paramount in clinical research to ensure compliance with regulatory standards and maintain the integrity of the research study. This section explores how consent contribute electronic forms to enhanced compliance through the implementation of audit trails and version control.

Audit Trail Transparency:

Electronic consent forms incorporate audit trails that provide a transparent record of all interactions and changes made during the consent process. These audit trails document when the consent form was accessed, modified, or reviewed, creating an accountable and traceable timeline of the entire consent journey.

Real-time Monitoring:

Audit trails allow for real-time monitoring of participant engagement with the electronic consent form. Researchers can track participant progress, ensuring that each section is completed and that participants spend an adequate amount of time reviewing critical information. This real-time monitoring enhances the overall compliance and quality of the informed consent process.

Identification of Modifications:

Version control within electronic consent forms identifies any modifications made to the document. This feature is crucial for tracking changes, ensuring that participants are always presented with the most up-to-date and accurate information. Researchers can easily identify and document alterations, minimizing the risk of using outdated or inaccurate consent forms.

Adherence to Regulatory Requirements:

Regulatory bodies often require thorough documentation and compliance with specific standards during the informed consent process. Electronic consent forms with robust audit trail capabilities enable researchers to demonstrate adherence to these regulatory requirements, facilitating a smoother auditing process.

B. Electronic Signatures

The integration of electronic signatures in the informed consent process represents a pivotal advancement, streamlining the documentation of participant consent. This subsection explores the advantages and implications of electronic signatures in clinical research.

Legally Binding Authentication:

Electronic signatures are legally binding, providing a secure and authenticated method for participants to signify their consent. This technology ensures the integrity of the consent process by linking participants to their specific agreement with the study terms and conditions.

Enhanced Security Measures:

Electronic signature platforms employ advanced security measures, such as encryption and authentication protocols, to safeguard the integrity of the consent document. These measures mitigate the risk of unauthorized access or tampering, reinforcing the overall security of participant consent records.

Efficiency and Expedited Consent Process:

Electronic signatures significantly expedite the consent process compared to traditional paperbased methods. Participants can sign consent forms remotely and promptly, reducing administrative delays and streamlining the overall timeline of the research study.

Traceability and Accountability:

Electronic signatures contribute to traceability and accountability by providing a digital record of when and where the consent was signed. This traceable trail enhances the auditability of consent process, demonstrating the the legitimacy of participant signatures and ensuring compliance with regulatory requirements.

C. Integration with Electronic Health Records

The seamless integration of electronic consent forms with electronic health records (EHRs) has far-reaching implications for research efficiency and data management. This subsection explores the benefits of such integration in enhancing compliance and documentation in clinical research.

Unified Participant Records:

Integration with EHRs allows for the creation of unified participant records, consolidating relevant health information with consent data. This integration ensures that researchers have a comprehensive view of participants' medical history and study-related interactions, contributing to more informed decisionmaking. Efficient Data Retrieval:

Electronic consent forms integrated with EHRs facilitate efficient data retrieval. Researchers can easily access and retrieve participant consent information alongside other pertinent health data, streamlining the research process and minimizing the time and effort required for data compilation.

Automated Documentation Updates:

Changes in participant health status or modifications to the study protocol can be automatically reflected in both the EHR and the electronic consent form. This automated synchronization ensures that all records are consistently updated, reducing the risk of discrepancies and enhancing overall compliance with study requirements.

Data Security and Privacy Measures:

The integration of electronic consent forms with EHRs necessitates robust data security and privacy measures. Adhering to strict protocols, such as encryption and access controls, ensures the confidentiality and integrity of participant data across both platforms, maintaining compliance with regulatory standards.

VI. Overcoming Challenges and Resistance

A. Addressing Technological Barriers

The integration of electronic consent forms into clinical research, while promising numerous benefits, is not without its challenges. This section explores strategies to overcome technological barriers that may impede the adoption and effectiveness of electronic consent processes.

User-Friendly Design:

Developing user-friendly interfaces is crucial to overcoming technological barriers. Ensuring that electronic consent forms are intuitively designed and easy to navigate caters to participants with varying levels of technological proficiency, promoting a seamless and accessible experience. Accessibility Features:

Electronic consent platforms should incorporate accessibility features to accommodate individuals with disabilities. This includes providing options for adjustable font sizes, compatibility with screen readers, and other adaptive design elements to enhance inclusivity and overcome barriers faced by participants with diverse needs.⁸

Training and Support Resources:

Offering comprehensive training resources and support materials can empower both participants and researchers. Clear instructions, video tutorials, and help desks can address technological concerns, providing assistance to those who may be less familiar with electronic platforms.

Pilot Testing and Feedback:

Before widespread implementation, pilot testing of electronic consent processes allows researchers to identify and address technological challenges. Collecting feedback from both participants and research staff during the pilot phase enables iterative improvements, ensuring a smoother transition to electronic consent methods.

Alternative Options for Participation:

Recognizing that not all participants may be comfortable with electronic methods, providing alternative options for consent, such as inperson or paper-based processes, can mitigate technological resistance. Offering flexibility in the consent process accommodates varying preferences and levels of comfort.

B. Ensuring Participant Trust

Establishing and maintaining participant trust is paramount in the success of any research study. This subsection explores strategies to overcome resistance related to concerns about data security, privacy, and the overall trustworthiness of electronic consent processes.

Transparent Communication:

Researchers should prioritize transparent communication about the security measures

implemented in electronic consent processes. Clearly articulating how participant data is protected, encrypted, and stored fosters a sense of transparency and helps build trust in the research process.⁹

Data Security Assurance:

Implementing robust data security measures and obtaining relevant certifications, such as ISO 27001, can serve as assurances of the commitment to safeguarding participant information. Demonstrating compliance with industry standards contributes to participant confidence in the security of electronic consent processes.

Educational Materials on Data Security:

Providing educational materials that explain the data security measures in place can alleviate participant concerns. Informative brochures, infographics, or video presentations can be used to convey the importance of data protection and the steps taken to ensure the confidentiality of participant information.

Ethical Review Board Endorsement:

Obtaining endorsement from ethical review boards for the use of electronic consent forms can enhance participant trust. Knowing that the research protocol and electronic consent process have undergone rigorous ethical scrutiny provides participants with additional assurance regarding the integrity of the study.⁷

Incorporating Participant Feedback:

Actively seeking and incorporating participant feedback throughout the research process, including the consent stage, demonstrates a commitment to participant perspectives. This iterative approach allows researchers to address concerns, adapt processes, and build trust collaboratively.⁸

C. Training and Education for Researchers

Researchers play a pivotal role in the successful implementation of electronic consent processes. This subsection explores strategies to address resistance stemming from a lack of familiarity or confidence among

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research staff in using electronic consent methods.

Comprehensive Training Programs:

Implementing comprehensive training programs for research staff ensures that they are well-versed in the use of electronic consent platforms. Training sessions can cover platform functionalities, troubleshooting common issues, and addressing participant inquiries, fostering confidence among research personnel.

Simulation and Mock Exercises:

Conducting simulation exercises or mock scenarios allows researchers to practice using electronic consent forms in a controlled environment. This hands-on approach helps build familiarity, identify potential challenges, and instill confidence in the use of technology during the consent process.

Continuous Support Mechanisms:

Establishing ongoing support mechanisms, such as help desks or dedicated support teams, ensures that researchers have access to assistance when needed. This continuous support minimizes barriers associated with technical challenges and allows for timely resolution of issues.

Peer Mentorship and Knowledge Sharing:

Facilitating peer mentorship programs or knowledge-sharing sessions among researchers can create a collaborative learning environment. Experienced researchers can share insights, tips, and best practices with their peers, promoting a culture of continuous learning and mutual support.

Feedback Channels for Improvement:

Creating channels for feedback and open communication allows researchers to share their experiences and challenges with electronic consent processes. This feedback loop can inform improvements in training programs, identify areas that require additional support, and contribute to the overall enhancement of research staff competency.

VII. Conclusion

The future of electronic consent forms in clinical research holds exciting possibilities, driven by technological innovations and a commitment to improving the participant experience. As the research community continues to embrace and refine electronic consent processes, the anticipated advancements aim to strike a balance between compliance, technological regulatory sophistication, and participant engagement, ultimately fostering a more ethical, efficient, and participant-friendly research landscape.

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