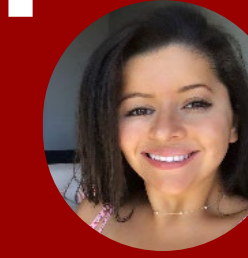


# E-Consenting Trial at Indiana University Simon Comprehensive Cancer Center

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## BACKGROUND

Utilizing electronic systems to e-consent would transform the consenting process at Indiana University Simon Comprehensive Cancer Center. The Clinical Trials Office (CTO) wanted a system to e-consent, bringing consenting into the digital age. Some of the major factors expected to be affected included compliance with regulatory requirements, consent tracking, data quality/accuracy, audit trails, and efficiency.

## GOALS

CTO wanted a uniform, accessible, secure and efficient consenting process. Utilizing a platform provided the opportunity to transition from paper consents to an electronic consent library. The shift would save physical space and be environmentally friendly (i.e. reduces paper usage). CTO focused on securely completing, submitting, and storing consents in a centralized location and enhanced process efficiency.

## SOLUTIONS & METHODS

CTO benefited from the ability to approach patients referred from various clinics. Through e-consenting, patients could review documents on their screens from home, eliminating the need to rush through the process in a clinic. This facilitated thorough review and allowed patients to ask questions without physical constraint or multitasking with clinic appointments.

E-consenting provided a secure method for completing/storing consents, which ensured data accuracy/legibility. Auto-populated fields, such as date of signature and consent version, ensured the correct consent version and provided legibility where patients' handwriting might be unclear.

## OUTCOMES

E-consenting provided challenges and benefits. Benefits included enabling the team to remotely approach and consent from multiple clinics. Being physically present in different clinics simultaneously was impractical, so the team utilized remote e-consent to complete consenting via phone or video call, leading to increased enrollment.

Patients lacking technological proficiency were evident. Some struggled to navigate the document, complete the identity verification process and submit. The platform required repeated identity confirmation before advancing to the consent form. Patients were given the option to navigate between message forms to enter codes sent for identity verification.

Transitioning to e-consent required training to adhere to system protocols, which was time consuming. Concerns arose about delays for patients in clinic during the process compared with the quicker paper consent method. Adopting e-consent required the team to carry laptops, connect to printers, download and print documents.

Despite the challenges, benefits included forced completion of all fields before submission. This played a role in ensuring no omitted information. The automatic filling of the date minimized the potential for error, something we encountered frequently using paper. The platform made sure staff consistently accessed the correct version of the document, providing accuracy and adherence to protocol.

## LESSONS LEARNED & FUTURE DIRECTION

In summary, e-consenting demonstrated significant advantages. However, we identified areas for improvement to enhance user-friendliness. As an example, there is a need to streamline the patient identity verification process by eliminating the multistep verification while upholding security standards. Additionally, improving navigation for patients who lack technological proficiency and may require remote assistance emerged as a key improvement area.

The CTO has opted to revert back to paper until a platform becomes available that meets consenting needs. The aims are to enable consenting efficiently and securely, prioritizing patient satisfaction and privacy.