E-consenting Trial at Indiana University Simon Comprehensive Cancer Center

N. Kassem

Indiana University Melvin and Bren Simon Comprehensive Cancer Center

1. 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.

2. Goals
The 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., reduce paper usage). The CTO focused
on securely completing, submitting, and storing consents in a centralized location and
enhanced process efficiency.

3. Solutions and Methods
The 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.

4. 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.

5. Lessons Learned and Future Directions
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 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.