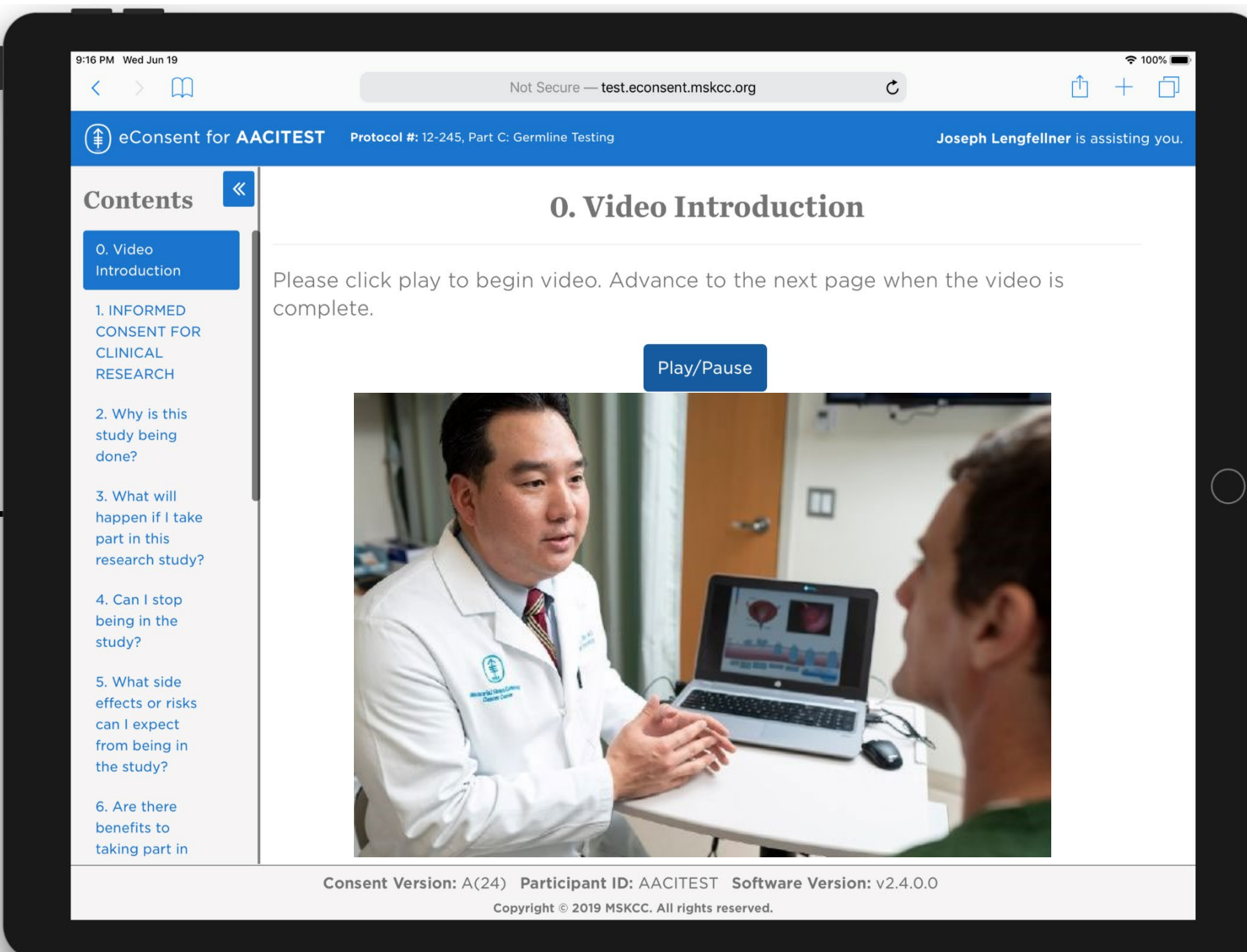


# Electronic Informed Consent (eIC) Platform for Clinical Trials: An Operational Model and Suite of Tools for Consent Authoring, Obtaining Informed Consent, and Managing Consent Documents

Joseph Lengfellner, Michael Buckley, Matthew Koch, Hector Pacheco, Joshua Levine, Carol Hoidra, Dorothy Damron, Collette Houston, Roy Cambria, Ann Rodavitch, Paul Sabbatini, Eric Cottington

## Background

The informed consent process is the foundation of human research subject protection, and studies have shown that enhancing the consent experience with introductory videos and visual aids can improve participant engagement and comprehension.<sup>1,2</sup> With this in mind, the MSK eIC platform was developed to augment educational alternatives for research participants, reduce administrative time and effort associated with paper-based consenting, improve the IC audit trail, and streamline consent document authoring.



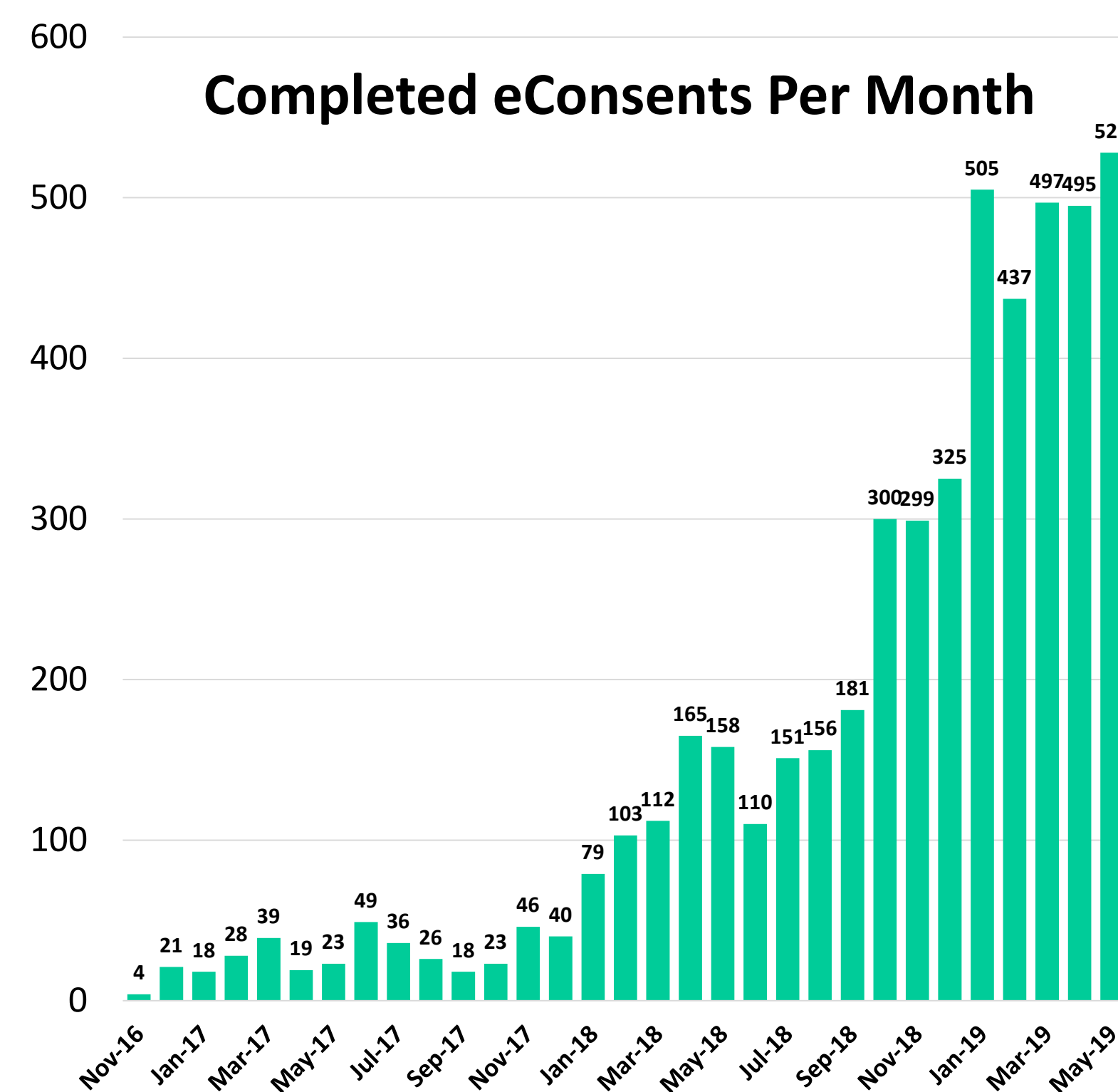
## Methods

This web-based platform is device and operating system-agnostic, built by the Clinical Research Informatics & Technology (CRIT) team at MSK.

To evaluate the pros and cons of the eIC platform versus traditional paper-based consenting, we assessed: 1) the availability of the finalized consent document in the electronic medical record (EMR), 2) processing time, and 3) the accurate completion of required data fields in the consent form. A standardized 5-question survey was used to assess research participants' feedback on the eIC process. Free-text response fields were provided for common topics. **Participants always drive the decision to use electronic or paper consenting.**

## Results

- >5,000 completed consents
- Used by 195 consenting professionals
- Across 36 different services

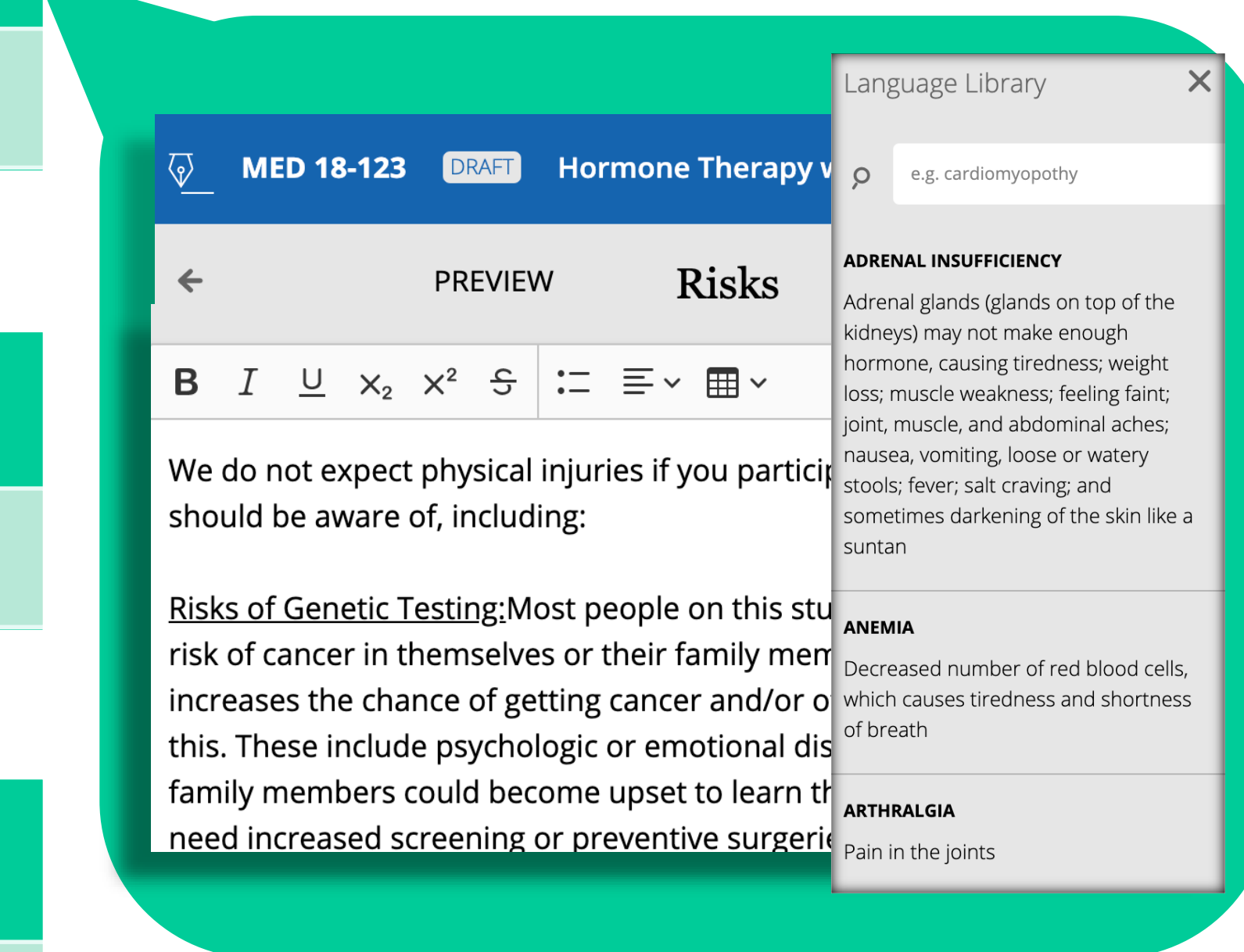
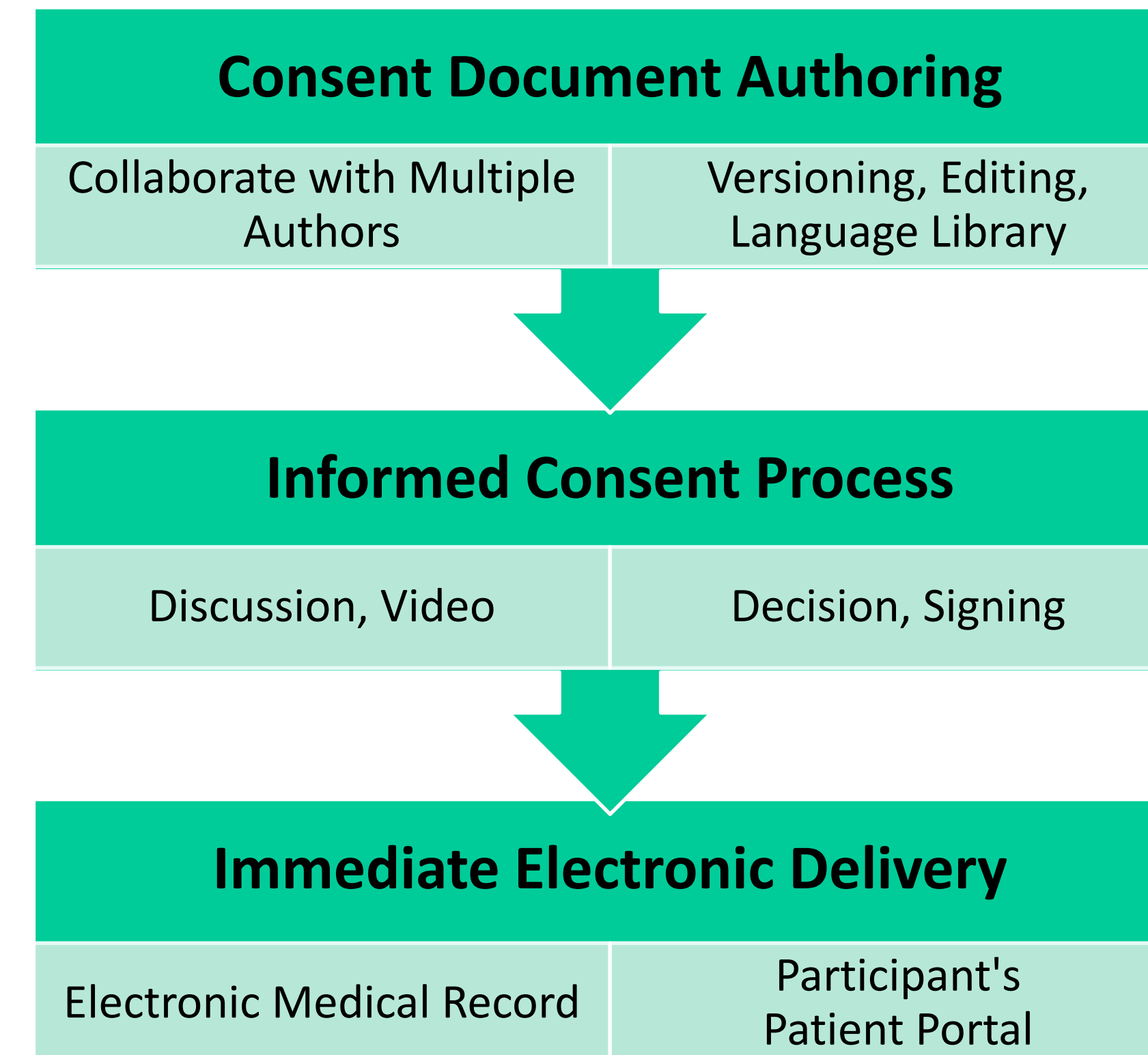


## Improves Quality & Compliance

We compared the results of 170 research participants who consented to at least one protocol during the same timeframe; 85 used the eIC platform, and 85 used the paper-based method.

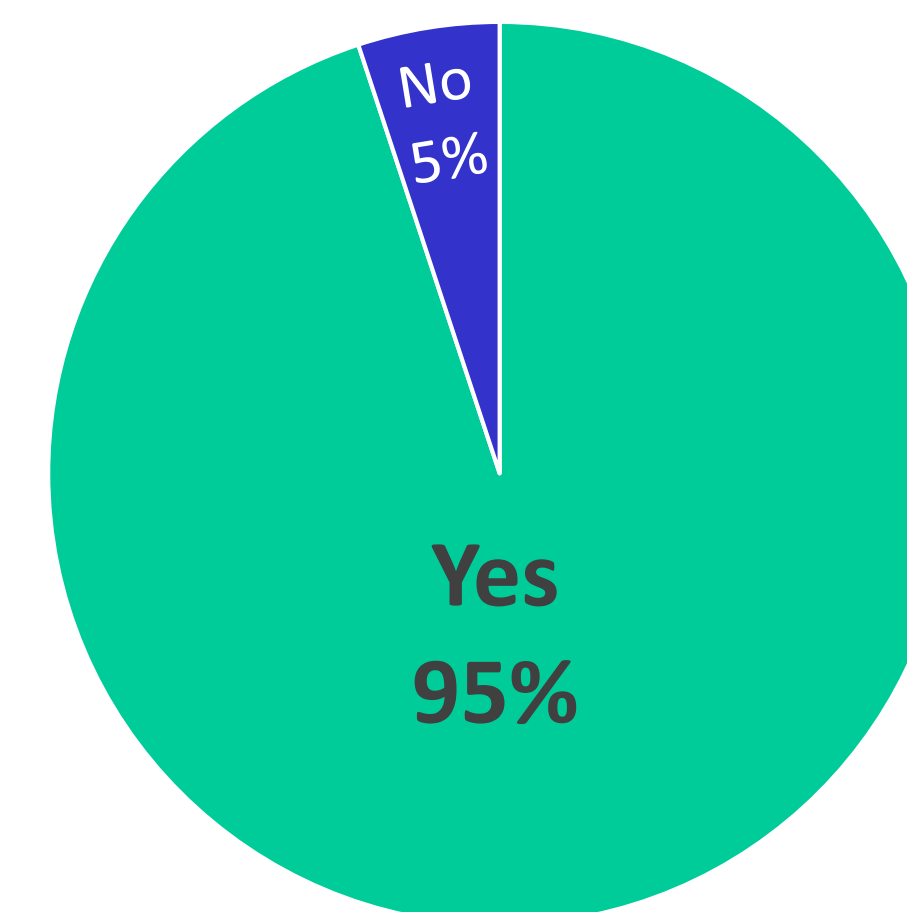
- **Use of the eIC platform increased the completion of required data fields in the consent form by 4%**, versus paper-based consenting.
- **The eIC platform decreases administrative effort** (collating, printing, scanning) associated with paper-based consenting by 5-15 minutes/form.
- **The platform delivers completed consent documents to the EMR within 2 minutes**, compared to up to 72 hours for paper consents.
- **The eIC module has a robust audit trail** that tracks the consent session and participant interactions via timestamps to indicate time spent in each section of the consent form.

## A Seamless Digital Experience: Consent Authoring → Delivery



## Patient Feedback

Would You Recommend eIC To Another Patient?



- **23% response rate** (365/1,577, as of 6/19/19).
- **81% of participants found the platform easy or very easy to use.**

Since February 2019, a standardized 5-question feedback survey was sent to each participant who completed a consent process using the eIC system.

## Buy or Build?

Off-the-shelf and Industry-specific solutions exist. **MSK decided to build a custom solution:**

1. **Tightly integrate with MSK systems**
2. **One platform for all consents**
3. **Consistent MSK brand experience**

## Future Platform Enhancements

- Multiple language support
- Ability to "hover" over term in consent to get further information
- Allow participant/provider to make notes on the electronic document during the consent discussion

### References

1. Rowbotham MC, Astin J, Greene K, Cummings SR (2013) Interactive informed consent: randomized comparison with paper consents. PLoS ONE 8(3): e58603.
2. Fink, AS., Prochazka, AV, Henderson, WG, Bartenfeld, D, Nyirenda, C, Webb, A, Berger, DH, Itani, K, Whitehill, T, Edwards, J, Wilson, M, Karsonovich, C, Parmelee, P. Enhancement of surgical informed consent by addition of repeat back: a multicenter, randomized controlled clinical trial. Annals of Surgery. 2010 Jul 252(1):27-36.