eConsent

Progress in eConsent solutions was slow, with the clinical research industry overdue to implement quick, secure, and flexible consent options. Most consent platforms were not 21 CFR compliant.

Then the COVID-19 public health crisis arrived and quickly became a major catalyst for eConsent adoption. The COVID-19 pandemic accelerated the rollout of eConsent.
eConsent

Electronic informed consent (eConsent) provides the same information, but in an electronic format.

Patient will have an option

It is important to note that eConsent is not meant to replace the important discussion between the patient and site staff.

As with traditional consenting, the site will continue to own the consenting process.
No matter the format for the informed consent process—paper or eConsent—the responsibilities set forth in the regulations related to the IRB and investigator have not changed.

- **Subject Recruitment**
- **Initial Telephone Screen**
- **continues throughout**
- **Through conclusion of study**
**Electronic Consent (eConsent)**

*mobile electronic consent with automated software platform*

1. **Informed Consent Process and Documentation**
   - Subject added in Invision IDX
   - HL7 message sent to FormFast
   - Subject added in FormFast Connect
   - Investigator (designee) activates subject in Connect and assigns the needed consent

2. **Email sent to subject**
   - 2FA to access eConsent

3. **Informed Consent Process and Documentation**

4. **Subject signs consent**
   - Investigator (designee) signs

5. **Informed Consent Process and Documentation**
   - Signed consent automatically sent to MedConnect and auto-associated with subject’s medical record
   - Copy of signed consent to subject
Benefits and Features of eConsent

- Content flexibility
- Role-based access
- Meets regulatory requirements
- Embedded educational links
- Version management
- Audit trails
- Dashboard status
- 21 CFR compliant

eConsent solution is fully compatible with any screen size and any device (e.g., phone, tablet, computer) and any browser (e.g., Apple Safari, Google Chrome, Microsoft Edge, Internet Explorer)
eConsent Roadmap

JANUARY 2022
• MHRI yearly mandatory research operations policy/procedure refresher training and introduced new eConsent procedure; training conducted on January 11 and January 13 with make-up training session on February 1
• Phased roll-out of new eConsent platform

2018
MHRI GUMC evaluation of eReg and eConsent systems

2019

2020
MHRI pilot (soft launch) of Interlace Health eConsent

2021
Rebuild and soft launch eConsent

2022
Active eConsents

17 Protocols
(17 Active eConsents sent to 545 subjects)

351 subjects
(old platform)

194 subjects
(new platform)
eConsent the New Standard?

The eConsent model can be a flexible, user-friendly, and secure solution to informed consent when built and used appropriately.

Long after social distancing ends, remote eConsent functionality will no doubt continue to address the growing adoption of decentralized and hybrid trial designs.
Thank You