

# IRBMED Guidance SignNow for Electronic Informed Consent Procedures

Remote and electronic informed consent (eIC) procedures are permitted by IRBMED when regulatory and institutional requirements of an in-person paper-based informed consent process are met. eIC refers to the use of electronic processes and systems to convey study information and/or to document informed consent from a participant or Legally Authorized Representative (LAR).

<u>SignNow</u> software is an E-Signature service available for use by U-M staff, faculty, researchers, and students associated with all University of Michigan campuses (i.e., Ann Arbor, Dearborn, Flint and Michigan Medicine). SignNow is HIPAA and FDA 21 CFR Part 11 compliant for patient signatures. Accounts for SignNow can be established free of charge until June 30, 2021 and is for individual use only. New users must <u>Request a New Account</u>. Links to U-M ITS training for SignNow are below.

## This service may be used to:

- ✓ Electronically prepare and send a research informed consent document (ICD) including HIPAA Authorization, when applicable
- ✓ Request and obtain digital signatures and other information on those documents
- ✓ Create 'SignNow Teams' able to sign, send, and manage documents across a group of people

# **Electronic Informed Consent (eIC) Procedures using SignNow**

- Upload ICD into the Documents folder of SignNow
- Prepare the ICD by adding appropriate fields to be completed
  - Add signers and enter a unique role for each signer (e.g. "participant", "LAR", or "PI")
  - o Include a *Printed Name* field next to or under the signature line
  - Add a Date/Time field for each signer
  - Additional fields such as *Initials* Field and *Checkbox* Field can be added to documents (e.g. for obtaining consent for optional research activities)
- Conduct consent process in-person or through messaging, phone call, or videoconference

## Additional Tips and Best Practices for using SignNow for eIC

- Require Signers to provide a password to access documents
- Use Chrome or Firefox to access SignNow
- Signers must have a SignNow User Account to download an ICD
- SignNow does not currently support assistive technology
- See additional <u>Best Practices</u>

#### Available U-M Information Technology Services Documentation and Training

<u>Sign Now Basics Quick Reference Guide</u>
U-M SignNow Documentation and Training – Includes How-to Videos