



U-MIC TRANSCRIPT

Using SignNow in Electronic Informed Consent:

Part one: overview

Electronic informed consent, or eIC, is the use of electronic processes and systems to convey study information to potential subjects or legally authorized representatives and to obtain and document their informed consent. IRBMED permits remote and eIC procedures provided that they meet the regulatory and institutional requirements of an in-person and paper-based informed consent process.

SignNow

SignNow is electronic signature software available for use by UM personnel and students from all University of Michigan campuses, including Michigan Medicine. SignNow is both HIPAA and FDA 21 CFR Part 11 compliant.

The SignNow system enables researchers to:

- prepare electronic informed consent and HIPAA authorization documents and send them electronically to potential subjects and study team members
- request and obtain subjects' digital signatures and other information on the electronic documents

eIC procedures using SignNow

The screenshot shows the 'U-M SignNow' page on the Information and Technology Services website. The page includes a navigation menu with categories like Computing, Communication, and Academics & Research. The main content area is titled 'U-M SignNow' and 'E-signature Service - SignNow'. It contains a 'Request a New Account' button, which is highlighted by a red arrow. Below the button is a 'SignNow Login' button. The page also includes a 'Need Help?' section with contact information for the ITS Service Center.

To create a SignNow account, UM personnel navigate to Information and Technology Services' U-M SignNow page and submit a request through the **Request a New Account** button.

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The screenshot shows the 'Getting Access to the E-signature Service - SignNow' page. On the left is a navigation menu with items like 'U-M SignNow Support', 'Documentation and Training', 'Best Practices', 'Known Issues', 'Service Status', 'User Registration Report', 'Important References', and 'Service Level Expectations (SLE)'. The main content area has a heading 'Getting Access to the E-signature Service - SignNow' and introductory text. A note states that the service is currently free for campus users but may become a charge in the future. Below the text is a form with fields for 'First Name', 'Last Name', 'Username', 'Unit/Dept Name', and 'Department Shortcode'. A red arrow points to the 'Department Shortcode' field. There are also radio buttons for 'Campus' selection (Ann Arbor, Dearborn, Flint, Michigan Medicine) and a 'Submit' button. On the right side, there are links for 'Request a New Account', 'SignNow Login', and 'Need Help?' with contact information for the ITS Service Center.

The new account page requires entry of a short code number to complete the request; however, no charges will be applied to the short code account for use of SignNow at this time. Users should check with their department administrators for the appropriate short code to enter in the SignNow account creation process.

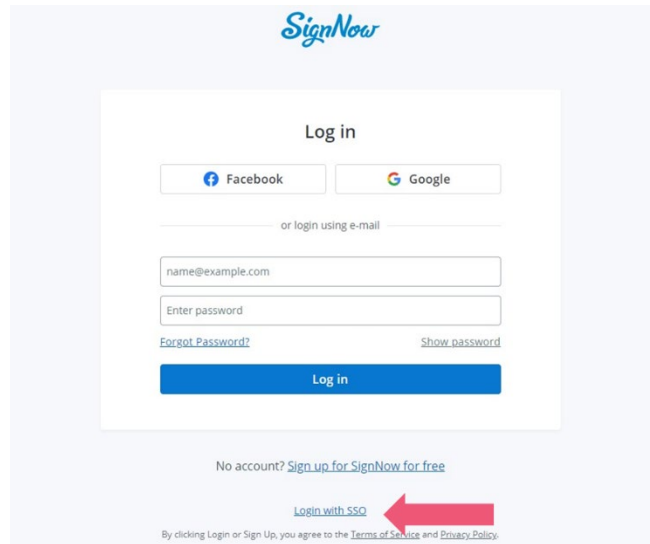
This screenshot shows the 'U-M SignNow' page on the University of Michigan's Information and Technology Services website. The header includes the university logo and navigation links for various services. The main content area is titled 'U-M SignNow' and 'E-signature Service - SignNow'. It contains the same introductory text and note as the previous screenshot. The 'Request a New Account' link is highlighted with a red arrow. Below it is the 'SignNow Login' button, also highlighted with a red arrow. The 'Need Help?' section provides contact information for the ITS Service Center.

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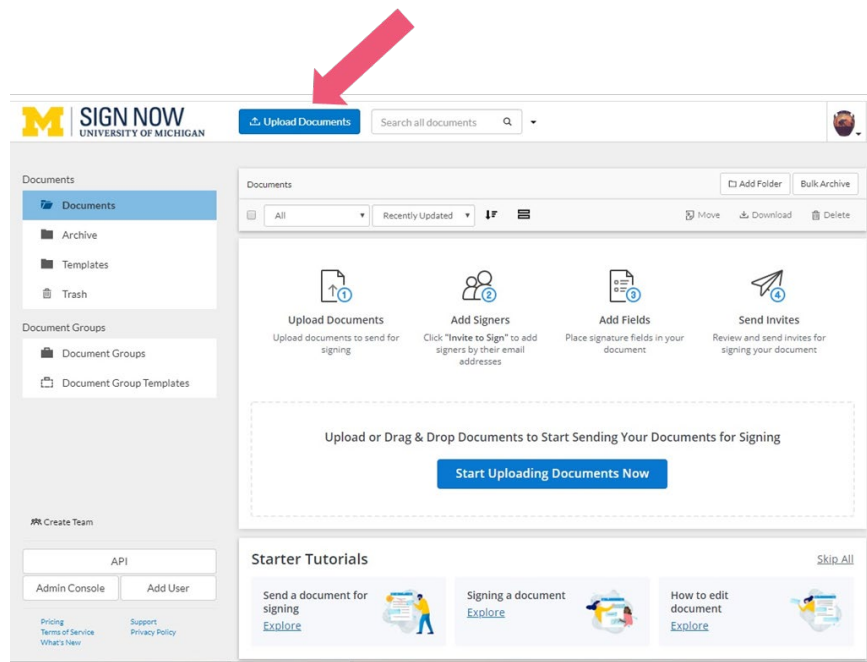
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Once ITS email notification of account access has been received, the user may access their UM SignNow account via the **SignNow Login** button.



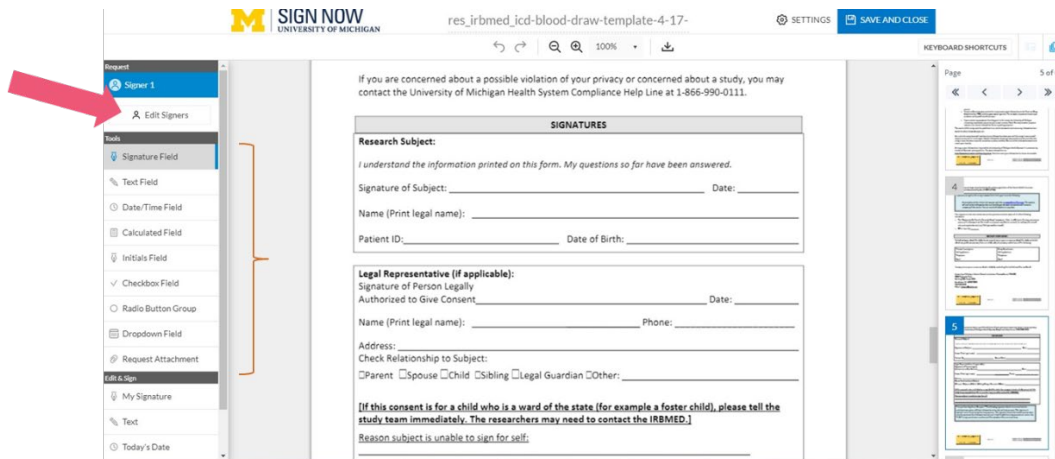
On the login page, UM personnel utilize the **Login with SSO** link, which enables users to sign in with their email address, without entering a password.



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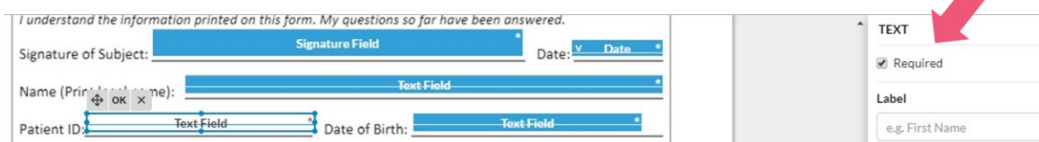
After uploading the IRB-approved consent document, the researcher must prepare it for an eIC process by first designating the applicable signers and then inserting *fields* within each signer's signature box.



These fields allow signers to electronically populate the document with signatures and other necessary information. To do this, the study team member selects, drops, and custom-sizes the appropriate field directly above each line that prompts for handwritten text.

SignNow contains numerous field types, each corresponding to a particular type of information. Field types include:

- **Signature field**
 - which enables the signer to type, draw, or upload their signature
- **Text field**
 - a free-text field most commonly used to populate a document's "printed name" lines
- **Date/time field**
- **Initials field and Checkmark field**
 - Initials or checkmarks may be used to document a subject's choice regarding optional study components, such as sub-studies or optional future use of samples and data.
- **other field types**



When a field is highlighted, a **Required** checkbox is visible in the upper right portion of the SignNow interface. If this box is checked, the signer will be required to populate the field in order to complete the signature process. In some instances, it is important to ensure that the **Required** box is *unchecked*; for example:

- Yes/no boxes to convey consent to optional study components; if these fields are inadvertently marked as required, signers will be forced to select both in order to complete the process

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- Boxes indicating a legally authorized representative's relationship to the subject; these must be non-required fields so that signers can check only the appropriate box and leave the others blank

The top screenshot shows the SignNow interface with a document titled "icd-blood-draw-template-4-17-2018-working_0". A red arrow points to the "Invite to Sign" button.

The bottom screenshot shows the "Invite to Sign" form. A red arrow points to the "Send Invite" button.

To:	Step	Role Name	E-mail Address
	1	subject	E-mail for subject
	2	researcher	E-mail for researcher

Once the document contains all appropriate fields, the researcher saves it to their account. From there, they use the SignNow system to email the document to all signers, by supplying the appropriate addresses in each email field and then clicking the **Send Invite** button.

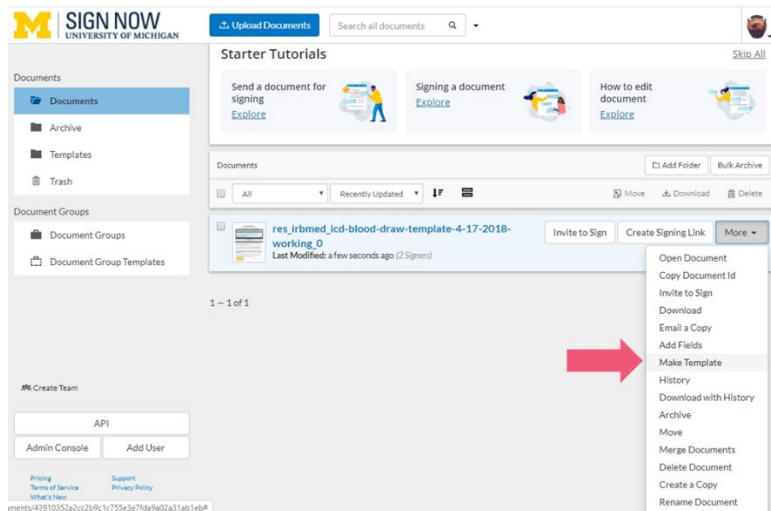
Points to consider

SignNow system requires action from all designated signers. Therefore, when preparing a document, be certain only to designate signers who will be involved in the consent process at hand.

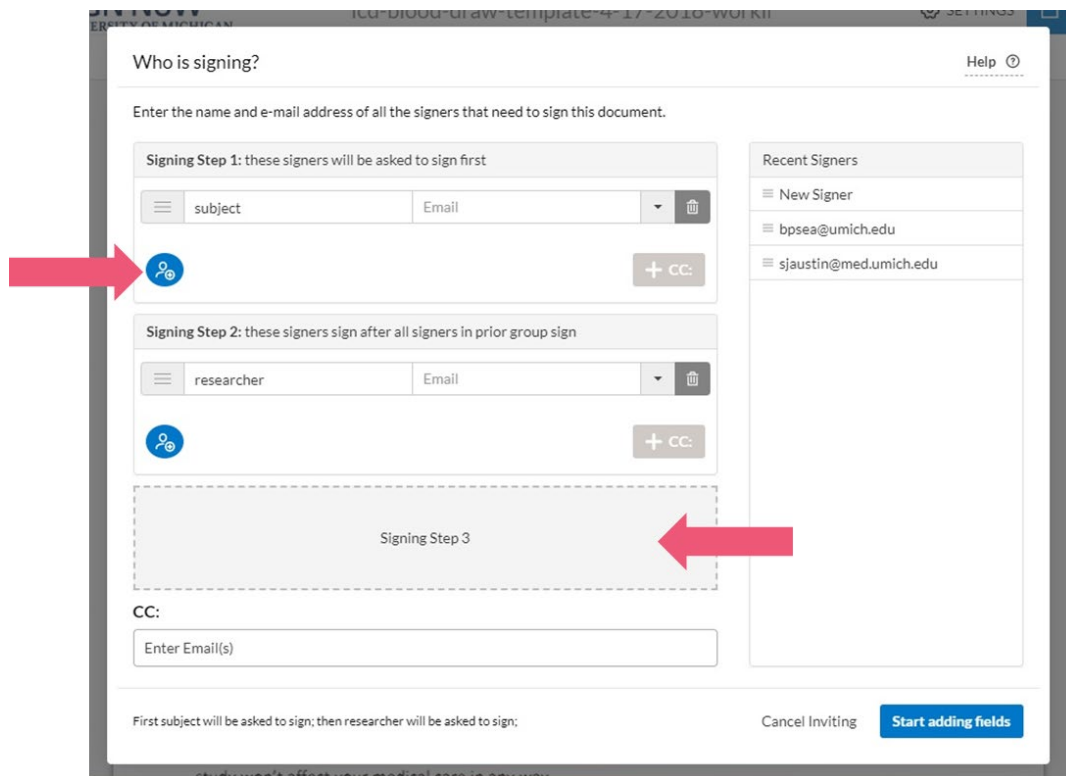
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To save researchers the time of preparing a new document for each potential subject, SignNow enables users to create and store template documents; templates can be prepared with all appropriate fields in advance so that they're ready for use when a potential subject is identified. When using templates, be certain that only the appropriate signers are designated in the document that signers receive. Part two of this presentation provides further details on managing SignNow templates.



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The SignNow system issues email invitations to designated signers in order of steps defined within the email invitation box.

Signers may be combined within a single step, meaning that the system will issue their email invitations simultaneously, or placed within individual steps, so that each signer receives an invitation only after the previous signer has signed the document. To promote clarity and efficiency in the signature sequence, IRBMED strongly recommends placing each signer in an individual step. Be sure to place the researcher role in its own *final* step, to ensure that the researcher signs the document last in the sequence.

UM's Information Technology Services department recommends using either Chrome or Firefox to access the online SignNow interface.

Part two of this presentation explores the use of SignNow templates to accommodate variable combinations of consent document signers. For more information about SignNow in electronic informed consent, contact Information and Technology Services or the IRB.

Posted May 12, 2020