What is iMedConsent™?

iMedConsent™ is a web-based application for securing consent including the electronic capture of signatures, both research consents, clinical procedure consents and most admission consents. The signature on consent documents can be obtained using a signature pad, mouse or touchscreen. The iMed process can be used when the consent is obtained in person or if the consent process is conducted remotely.

iMed consent is accessed via CRIS, which allows the completed consent with signatures to be viewable in CRIS within a few minutes of completing the consent and signature process. No more "lost" signed consents! Note that if using the NIH Off Site consent to enroll participant that are not coming to or using NIH Clinical Center (CC) resources, you will not be able to use iMed as the participant doesn't have a CC Medical Record Number.

Your research protocol must specifically allow for the use of iMed consent. If the protocol allows for iMed consent, this is the preferred method (versus using a paper consent).

Resources for iMedConsent™ Process:

Please review the following before you use iMed consent:

Resources via the CRIS Education Resources > Communication with Other Staff and Patients > iMed Consent

- iMedConsent™ User Guide
- iMedConsent™ FAQs
- iMedConsent™ Training Video
- iMedConsent™ Patient Instructions Video (2 minutes) – Send this link to patients to review prior to obtaining consent

Training classes are also available via iMedConsent™ HIMD Training

Important:

The signature of the investigator obtaining consent must be done after the participant, parent and/or LAR signature/initials are captured in the iMed system. Please ensure that signatures and initials (patient, parent, LAR) are appropriately captured on the iMed consent prior to the investigator signing consent. To check if signatures have been captured on the iMed consent, click on the Signature tab. A date and time will be noted next to the signatures that have been captured, with the Signature of PI/AI marked as Incomplete. If a witness signature is required, that must also be done after the participant, parent and/or LAR signature/initials are captured.

000050 C 1 Affected Participants			
Input Signature Document			
Initial for Yes:	Sign	iMed MSC	11/23/2022 at 08:47:50
Initial for No:	Sign	iMed MSC	11/23/2022 at 08:55:18
Participant - Sign:	Sign	iMed MSC	11/23/2022 at 08:57:13
Investigator - Sign:	Sign	iMed MSC	*Incomplete*

Helpful Tips:

- Use a test patient in CRIS to review the consent(s) prior to consenting a registered patient.
  - A test patient can be found by searching last name of "NIHCCTEST" in CRIS and choosing any test patient that has an MRN that starts with a 7 or 8.
  - Choose all available scenarios (ex. Check boxes, initials, signatures) on the input form to ensure that they are clear and appear as you expect on the document tab.
  - Note – when choosing different options on the Input tab in the same session (without saving), some of the previous signature items will appear. Please close and re-open the consent.
- When in the iMed system (via CRIS), under Favorites tab, save all of your team consents, 01C0129, 04C0165 and most commonly used short form consents for easy access.
- Send the patient the Patient Mobile Signature Education video referenced above if they have not used mobile signature function previously.
- You must review the consent document in the Document tab in iMed (to make sure the correct one was chosen, and it is the correct version of the consent) prior to obtaining any signatures, and then review it again prior to saving a completed document as it is the last time any changes can be made.
- The patient, and if applicable the witness, must sign/initial the consent PRIOR to the investigator signing consent. iMed dates and times the signature.
- If you have a protocol modification/amendment approved that contains a new consent and you need to have it available quickly, you need to reach out to "CC-HIMD iMed Support" in Global and request the modified consent be uploaded in iMed.
- If your clinic does not have a signature pad you can use the remote signature option even if you are in person.
- The signed consent will automatically load into the patient portal, but you still need to offer to print or secure email a copy to the participant and document the patient's preference for a copy of the signed consent.
- If you make a mistake in iMed after you save the consent it cannot be modified - you will have to explain in your documentation of research consent note. Please contact CCR OEC for questions.
- If you don't see your consent in iMed, please contact Liz Ness.