Michigan Medicine COVID-19 Research Informed Consent Procedures

Informed consent of the patient or their legally authorized representative (LAR) is necessary before enrollment in a clinical trial. Obtaining consent from hospitalized COVID-19 positive patients (or those undergoing testing) must be conducted in a manner that reduces the potential for viral transmission between individuals, preserves personal protective equipment (PPE), and accounts for whether the patient has the capacity to give consent as well as their physical ability to sign informed consent documents.

The following procedures represent the preferred methods at Michigan Medicine for obtaining research informed consent from a hospitalized patient or their LAR. However, study teams must follow informed consent procedures as approved by the IRB with oversight for the study taking into account federal requirements (i.e., FDA, OHRP, HIPAA, etc.). Study teams must work with clinical care teams to assess the following options and select the method most appropriate for each individual patient. These methods may also be applicable in outpatient settings that include COVID-19 patients.

Note: The 'Wet Ink Signature / No Photo' and 'No Signature' methods are not to be utilized outside of COVID-19 circumstances as they represent FDA guidance for obtaining consent during the pandemic."

1. **Electronic signature (SignNow)**
   Patients Able to Sign Informed Consent Electronically

2. **Wet Ink Signature on Paper**
   Patients Able to Sign a Paper Informed Consent but Unable to Sign Electronically

3. **No Signature**
   Physically Challenged Patients Able to Give Informed Consent but Unable to Sign a Consent Form

   - **Attachment 1: Informed Consent Coversheet**
     Explanatory language for the patient when the clinical care team takes a blank informed consent document into a patient's room.

   - **Attachment 2: Study Team and Witness Attestation Form**
     For use with the SignNow process.

IRBMED is available to answer any questions about these procedures. Contact information: irbmed@umich.edu or 734-763-4768.

1. Electronic signature (SignNow)

Premise

This FDA and HIPAA compliant electronic signature process permits informed consent materials to be uploaded to the SignNow platform and routed via email for review and signature to the patient, LAR, study team members, and any necessary witness. Signature lines (including date and time-stamps) are affixed to the consent forms within the SignNow platform. Routing information is included during document set-up. Individuals access the document via email to complete the signature process.

Resources

- To set up a SignNow account and obtain training information:

  https://its.umich.edu/projects/e-signature/node/3

- IRBMED guidance on eConsenting:

  https://az.research.umich.edu/medschool/guidance/informed-consent-procedures-using-electronic-systems-and-remote-use-paper

- FDA Guidance on electronic documents and electronic signatures
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application

How to use

Patient Electronic Signature

a) The patient must have access to email via a smartphone or computer to view the informed consent documents and apply their electronic signature. Due to current infection control procedures, the patient's device must be used as one will not be provided by Michigan Medicine.
b) Generally, the study team will conduct the discussion with the patient by calling the patient's smartphone or hospital-room telephone.
c) It is recommended that the clinical care team, at their earliest convenience, provide the patient with a paper copy of the unsigned consent document and any accompanying explanatory coversheet prior to the call from the study team. While the consent document is available in SignNow, it may be easier and more efficient to discuss the study with the patient if they can view a paper copy. The paper copy will be disposed of at an appropriate time, according to infection control standards.
d) After the patient's questions have been answered by the study team and they agree to participate, the patient will utilize SignNow on their electronic device to complete the signature process.
e) The electronic copy of the signed document will be placed into MiChart and the study's research records. Assure the patient receives a signed electronic copy via SignNow.

LAR Electronic Signature

This same process can be used with the LAR, when applicable, if they possess an electronic device capable of receiving email. If an LAR cannot utilize the SignNow process, select another appropriate option in this document.

2. Wet Ink Signature on Paper

Premise

Not all patients possess an electronic device such as a smartphone or computer to complete the electronic SignNow process. Some patients possessing a device may not feel well enough to perform necessary electronic functions to complete the tasks. These patients may still be able to sign a paper copy of the informed consent document.

Resources

- FDA Guidance 2020:
  FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic

- IRBMED Guidance:
  https://research.medicine.umich.edu/our-units/institutional-review-boards-irbmed/informed-consent-assent-templates

How to use

Patient Wet Ink Signature on Paper
(These steps encompass FDA's 2020 guidance for obtaining a wet ink signature during the pandemic)

a) At their earliest convenience, the clinical care team provides an *unsigned* consent form (with any applicable explanatory coversheet) and pen to the patient. In order to meet infection control standards, the paper documents and pen must not leave the patient's room.
b) If direct communication with the patient is not feasible or safe, the study team calls the patient's mobile phone or hospital-room telephone and arranges a three-way call or video conference with the patient, an impartial witness, and if desired and feasible, additional family or friends as requested by the patient.
[*Note*: The impartial witness cannot be the same person conducting the informed consent discussion. An individual who also happens to be an LAR may be considered the impartial witness in this process, but in their role as a witness they are only witnessing the patient's agreement to participate in the research study and are not signing on behalf of the patient.]
c) Before proceeding, all participants on the call or video conference should identify themselves.
d) The study team member (PI or designee) reviews the informed consent document with the patient and responds to any questions from the patient.
e) The witness confirms that the patient's questions have been answered.
f) The study team member confirms that the patient is willing to: 1) participate in the trial and 2) sign the informed consent document while the witness is listening on the phone.
g) The patient provides verbal confirmation that they: 1) would like to participate in the trial and 2) that they have *signed and dated the informed consent document that is in their possession*.
h) If the signed informed consent document cannot be collected from the patient's location and included in the study records, FDA considers the following options as acceptable documentation that the patient signed the informed consent document:
    - Attestations by the witness who participated in the call and by the investigator that the patient confirmed that they agreed to participate in the study and signed the informed consent. Either:
        - Complete the informed consent document if it includes a signature line for the witness (do not sign as the LAR)

- Or, sign the Study Team and Witness Attestation Form (Attachment 2) via SignNow

OR

- Take a photograph of the informed consent document with attestation by the person entering the photograph into the study record that states how the photograph was obtained and that it is a photograph of the informed consent document signed by the patient. (This requires use of the patient's electronic device in the room *or* a photograph taken from outside the room if the signature page of the informed consent document can be held up to the window. Make every effort to capture the version number of the consent document in this photograph.)

i) Place the following materials in MiChart and the research study's source documentation:
   - A copy of the full informed consent document signed by the study team and witness (if there is a witness signature line) and a photograph of the patient signature (if any) OR
   - A copy of the full informed consent and the Study Team and Witness Attestation Form prepared via SignNow (Attachment 2) AND
   - A notation by the investigator of how the consent was obtained (e.g., telephone) and how it was confirmed that the patient signed the consent form (i.e., either by attestation of the witness and investigator or the photograph of the signed consent). The note should include a statement of why the informed consent document signed by the patient was not retained (e.g., due to contamination of the document by infectious material).

j) A copy of the informed consent document is available to the patient (now research participant) via a medical record request from MiChart.

LAR Wet Ink Signature on Paper

a) Provide the unsigned informed consent document to the LAR. Methods include, but are not limited to:
   - Mailing a paper informed consent document to the LAR
   - Giving a paper informed consent document to the LAR if the LAR is present per hospital visitor guidelines or is also an inpatient
   - Emailing or faxing an electronic copy of the informed consent document (Note: if the LAR has access to email, SignNow is the preferred method.)

b) Conduct the informed consent discussion and answer questions from the LAR prior to obtaining LAR signature on the informed consent document. Methods permitted include, but are not limited to:
   - A conversation via telephone
   - A conversation via telehealth or other secure video technology
   - Use of chat technology

c) The LAR must return the signed informed consent document to the study team. The most timely and acceptable methods include, but are not limited to:
   - Taking a picture of the signature page via a smartphone or camera, and sending the picture back to the study team via email or text message
   - Scanning the signature page of the informed consent document and electronically returning to the study team via email
   - Faxing the signature page back to the study team

d) Place the following materials in MiChart and the research study's source documentation:
   - A copy of the full informed consent document and the image of the signature page signed by the LAR and a signature page signed by the person obtaining consent. The individual obtaining consent may sign/date on the same image as the LAR or a print a clean version of the signature page. The study team signature could also be applied via the SignNow process. AND
   - A notation by the investigator of how the consent was obtained (e.g., telephone).

e) A copy of the informed consent document is available to the patient (now research participant)/LAR via a medical record request from MiChart.

3. No Signature: Physically Challenged Patients Able to Give Informed Consent but Unable to Sign a Consent Form

Premise

The FDA permits a person who is physically challenged (for example, unable to write) to enroll in a clinical investigation if they are otherwise *competent and able to signal consent* (rather than sign a document) when consistent with applicable State law. FDA recommends that the subject's case history include a description of the specific means by which the prospective subject communicated agreement to take part in the clinical investigation and how questions were answered. FDA also recommends that investigators accommodate the specific needs of the study population.

Study teams must work with clinical care teams to assess this option as appropriate for each individual patient. Circumstances precluding the patient's ability to sign a paper or electronic document may include medical devices obstructing their manual dexterity or other physical challenges.

This process is not a regulatory waiver of documentation of informed consent and does not use an LAR to sign on behalf of the patient. If patients are not competent to give consent, the LAR process must be utilized.

Resources

- FDA Guidance 2014:

  Informed Consent Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors

- FDA Guidance 2020:

  FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic

How to use

Patients Able to Give Informed Consent but Unable to Physically Sign a Consent Form

a) At the earliest convenience, the clinical care team provides an *unsigned* consent form (with any applicable explanatory coversheet) and pen to the patient. In order to meet infection control standards, the paper document must not leave the patient's room. An electronic copy of the document may also be sent to the patient (e.g., by email).
b) If direct communication with the patient is not feasible or safe, the study team member contacts the patient by calling the patient's smartphone or hospital-room telephone and arranges a three-way call or video conference with the patient, an impartial witness, and if desired and feasible, additional family or friends as requested by the patient.

   [*Note*: The impartial witness cannot be the same person conducting the informed consent discussion. An individual who also happens to be an LAR may be considered the impartial witness in this process, but in their role as a witness they are only witnessing the patient's agreement to participate in the research study and are not signing on behalf of the patient.]
c) Before proceeding, all participants on the call or video conference should identify themselves.
d) The study team member reviews the informed consent with the patient and responds to any questions from the patient.
e) The impartial witness confirms that the patient's questions have been answered.

f) The patient provides verbal confirmation to the study team and the impartial witness that they would like to participate in the study.

g) The study team and the witness provide attestations to document the patient confirmed their decision to participate in the study. Either:
- Complete the informed consent document if it includes a signature line for the witness (do not sign as the LAR)
- Or, sign the Study Team and Witness Attestation Form (Attachment 2) via SignNow

h) Place the following materials in MiChart and the research study's source documentation:
- A copy of the full informed consent document signed by the study team and witness (if there is a witness signature line). This may be wet ink or via SignNow. OR
- A copy of the full informed consent and the Study Team and Witness Attestation Form prepared via SignNow (Attachment 2) AND
- A notation by the investigator of how the consent was obtained (e.g., telephone), how questions were answered, that there was an impartial witness to the discussion, that the patient gave verbal consent, and why the patient was not able to provide a signature on the consent document.

i) A copy of the informed consent document is available to the patient (now research participant) via a medical record request from MiChart.

LAR Able to Give Informed Consent but Unable to Physically Sign a Consent Form

There may be circumstances when an LAR intends to provide consent on behalf of a patient who is unable to give informed consent, but the LAR is physically incapable of signing an informed consent document (e.g., they may be hospitalized and facing the same circumstances as outlined in the *patient* scenario above). The study team should follow the procedures outlined for the patient to secure the consent of the LAR.

Attachment 1: Informed Consent Coversheet

Explanatory language for the patient when the clinical care team takes a blank informed consent document into a patient's room.

INFORMATION ABOUT PARTICIPATING IN A COVID-19 RESEARCH STUDY

The University of Michigan has identified you as a patient that may be eligible to participate in a research study related to COVID-19. The information below describes the process for learning more about this research.

- The research informed consent document contains a telephone number for the research study team (usually near the end of the document). You can call that number to let the study team know of your interest in learning more information about the study.
- The study team will also try to call you on your mobile phone or on your in-room hospital telephone to talk with you about the study.
- You can tell the study team you would like to have a family member or friend on the call and they will make the arrangements to the best of their ability. An additional person from the University of Michigan may also be on the call to assure that all of your questions have been answered. If a family member or friend is not able to be on the call, this is required.
- During the telephone call with the study team, you can review the consent document and learn more information about the study. You can ask any questions about the study.
- If you want to be in the research study and the study team says you qualify, the study team will talk with you about the process for giving your permission.

Attachment 2: Study Team and Witness Attestation Form

For use with the SignNow process

Print or Type Each of the Following:

Patient Name:

MRN number:

eResearch Study Number:

Study Team Member:

Your signature on this form indicates you provided information about the aforementioned research study to the patient named on this form. You explained:

- The research procedures,
- The risks and benefits of participating in the research, and
- You answered the patient's questions to the best of your ability.

Impartial Witness:

Your signature on this form indicates you were present as the study team member explained the research study to the patient named on this form. You heard the study team member explain:

- The research procedures,
- The risks and benefits of participating in the research, and
- They answered the patient's questions.

Name of Study Team Member:

_____

Signature of Study Team Member/Date/Time:

_____

Name of Impartial Witness:

_____

Signature of Impartial Witness/Date/Time:

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