Informed Consent for Invasive Procedures

Frequently Asked Questions – October 4, 2023

Informed consent is a process of communication between a provider and patient to reach agreement or permission to perform a procedure. The patient (or designee) signature on the form confirms that a provider has:

- reviewed the procedure
- discussed the risks, benefits, and alternatives
- answered all the patient or designee questions

Frequently Asked Questions:

What policy do we follow?

- Policy can be found by accessing Policy Stat on the MHC Intranet Homepage under resources/tools: Viewing Informed Consent - Diagnostic or Therapeutic Procedures and Treatments (policystat.com)

What is the responsibility of the provider?

- A provider is considered a physician, a nurse practitioner, a physician assistant, a certified nurse midwife, or a CRNA.
- The provider is responsible to discuss the procedure: its risks, benefits, and alternatives, and to answer all patient or designee questions. The provider will document the discussion in the patient's medical record and place an order for the procedure.
- Ideally the provider and patient will both sign the consent form at the time of the informed consent discussion. For some patients, the provider obtaining the consent and the provider performing the procedure are the same person and at other times they are not. The signature of the provider performing the procedure is required on the form confirming that the informed consent process has been completed. The provider performing the procedure may sign the consent form after the discussion during the office visit, in the patient room, **OR** in the procedural area prior to the start of the procedure.

What is the responsibility of the acute care RN?

- The nurse serves an important role in this process to optimize patient care and workflow.
- Enter the procedure on the consent form using NO abbreviations, or if available, use the procedure specific consent form.
- If the informed consent discussion occurred with the provider, but the provider did not sign the form at the time of the discussion - nursing personnel may facilitate signature of the patient or the designee ONLY in situations where the patient or designee has no questions.
- Confirm that the form is placed in the patient's chart and travels with the patient to the procedural area. If there is no provider or patient signature, inform the pre-procedure staff during hand-off communication.

What is the process for completing a telephone consent?

- Telephone consent is for situations in which the patient cannot give consent and their designee is not physically present. The designee is contacted to obtain verbal confirmation to perform the procedure.
- A witness is NOT required for telephone consents.
- The provider obtaining the telephone consent signs the consent form.
- The provider places a note in the patient record of the informed consent discussion with the designee by telephone. Procedure orders are placed.

Telephone consent obtained from John Doe, Husband Kathy Jones, RN March 2, 2023 5:15 pm		
SIGNATURE OF PATIENT/PARENT OF MINOR/LEGAL GUARDIAN OR REPRESENTATIVE (RELATIONSHIP, IF NOT PATIENT)	DATE	TIME
Mary Smith, MD	March 2, 2023 5:15 pm	
PROVIDER SIGNATURE	DATE	TIME

Can the patient sign the consent form with the risks section blank and PRIOR to the provider signing?

- Yes. The provider is responsible to provide the risks, benefits, and alternatives as part of the informed consent conversation and document this on the form or in the patient's medical record. The form has common risks listed, e.g., bleeding, infection. The provider determines if additional risks need to be added to the form.
- The patient/designee may sign the form prior to the provider signature if they state to the clinical staff the informed consent process has been completed AND they do not have questions.

What should I do if a provider refuses to sign a consent form or complete the 90-day extension section?

- Escalate to your manager to discuss with the provider. If no resolution, escalate to your CMO.

How long is the consent 'good for'?

- Consents are valid for 90 days. Time frame for a "valid" signature increased from 30 days to 90 days, with an *additional* 90-day signature, if needed.
- This extension should assist with surgical start times decreasing delays due to need to 're-consenting' the patient.

Is there more than one informed consent form?

- Most consent signatures will occur on Form 303. Procedure-specific consents are being developed for high-volume procedures and will contain preprinted risks, benefits, and alternatives as developed by the providers to reinforce discussion contents.

What do we do with our old forms?

- Purge! If you find any consent forms without the option for the provider signature, please purge.

Has the consent process changed for blood product administration?

- The consent process for blood administration currently remains the same but is under review as inconsistencies in the process have been identified.
- The RN leads the informed consent discussion and completes the form.
- Blood Transfusion Consents are valid for 30 days Transfusion Policy

Questions?

Clinical questions: Dr. Joe Santangelo
Regulatory questions: Suzanne Carlson
Process questions: Cathy Munoz

Informed Consent for Invasive Procedures – New Process - March 1, 2023

Purpose: To improve patient safety, patient satisfaction and align with regulatory standards

Definition: Informed consent is a ***process*** whereby a patient (or in the case where a patient lacks capacity or competency, the patient's authorized representative) makes an informed decision about a procedure, care, treatment and services based on direct communication with the provider performing the procedure regarding the proposed course of treatment that includes a clear, concise and factual explanation of proposed procedure, care, treatment and services, possible outcomes and alternatives to therapy.

Why change? Ongoing recommendations from consultants, a previous citation from TJC as well as patient safety events related to correct procedure, correct patient presented us with the opportunity to review our entire informed consent process. By improving our informed consent process, we have the potential to increase staff efficiency, ensure accurate documentation, enhance physician-patient communication, and improve overall patient safety and satisfaction.

This new procedure will support patients in medical decision making by having a clear understanding of the risks, benefits, and alternatives prior to a procedure while also protecting providers from concerns regarding informed consent by providing clear documentation of agreement between the provider and the patient.

- Eliminate low-usage non-compliant procedure-specific forms
- Consolidate different versions of procedure-specific forms that are being used at various locations into 1 form to be used at all locations for that procedure
- Clarify the approval process when requesting a new procedure-specific consent

What changed?

- Consents will be valid for 90 days
- Signature of the provider on the form is now required.
- Inform Consent Form changes:
    - Addition of physician signature
    - Deletion of witness signature – previously MHC Staff signature
        - Template informed consent form available:
            - MHC For Providers | Forms
            - MHC Online Forms - MHC Confirmation of Informed Consent for Procedure - 0303 - All Documents (sharepoint.com)
- Ambulatory – reinforce consistent practice of obtaining the patient signature at the time of the informed consent discussion while in the provider's office.
    - The informed consent will be sent to the hospital at the same time as the H&P and other required pre-op documentation
- Inpatient:
    - Assistance to the provider assuring form is available for the discussion

What has NOT changed –

- The responsibility of obtaining the informed consent discussion remains with the provider
- Nursing may continue to facilitate signature of the patient or their representative ***IF*** the patient reinforces the informed consent discussion occurred with the provider and they have no questions
- Form travels with the patient to procedural area

Action requested:

- **Ambulatory:** When the informed consent discussion for a hospital procedure happens in a provider office, the new informed consent form (signed by the provider and patient) will be faxed to the hospital with other pre-operative paperwork.
- **Acute Care:** The new form will be signed at the time that the proceduralist has the discussion with the patient. This could occur on the inpatient floor or at the site of the procedure.
- Pre-procedure checklist should include confirmation of patient and provider signatures.