Administrative Policy
POLICY NO. 200.02.104A

POLICY TITLE: Informed Consent

Submitted by: Dr. Yolangel Hernandez Suarez, MD, MBA
Title: Vice Provost for Population Health and Well-being and Associate Dean for Clinical and Community Affairs

Approved by: Quality Improvement Patient Safety Committee (QIPSC)

Committee Chair: Dr. Yolangel Hernandez Suarez, MD, MBA
Title: Vice Provost for Population Health and Well-being and Associate Dean for Clinical and Community Affairs

Creation Date: 12/03/2018
Effective Date: 09/19/2019
Review Date:
Revision Date: 09/19/20**22**

SUMMARY & PURPOSE: Informed consent assures that the patient is given information related to their care in a manner that is understandable to them. The informed consent process acknowledges the patient's right to ask questions and to make an informed and voluntary decision as to whether to undergo a proposed procedure, intervention, or type of care.

SCOPE/APPLICABILITY: This policy applies to all the HWCOM Clinical Locations and, affiliated institutions where faculty, students and /or staff provide care to patients. The HWCOM clinical locations are: FIU Health Modesto Maidique, ("MMC"), FIU Health Broward, Green Family Foundation NeighborhoodHELP Mobile Health Centers and Household visits and the Linda Fenner 3D Mobile Mammography Center.
For the faculty, students and staff that are located in the *affiliated* hospitals, and outpatient centers the policies and procedures of those institutions will govern their reporting responsibilities.

POLICY: An informed consent is obtained for all clinical treatment where disclosure is required regarding medical information, a planned procedure, that includes discussion regarding the risks, benefits, and alternatives. After the discussion occurs with the provider, the patient can choose to proceed, consider an alternative or cancel the proposed treatment. The informed consent process is led by the provider and witnessed by a staff member. The informed consent *must* never be delegated to a staff member.

DEFINITIONS:

Informed Consent: A process of communication between a provider and the patient that results in the patient's authorization or agreement to undergo a specific medical or consented procedure. Informed consent assures that the patient is given information related to their care in a manner that is

understandable to them. The informed consent process acknowledges the patient's right to ask questions and to make an informed and voluntary decision as to whether to undergo a proposed procedure, intervention, or type of care.

EMR: Electronic Medical Record

Preferred Language: This is the language the patient is most comfortable in communicating with their provider. The patient will sign the consent form in their *preferred* language. (English, Spanish, Creole, other).

Adverse Incident: An event that causes or has the potential to cause an unexpected or unwanted effect involving the safety of a patient, whether an injury has occurred. HWCOM faculty and staff will complete an incident report for adverse incidents. Examples of adverse incidents include but not limited to the following: performing a procedure on the wrong patient, wrong procedure, or incorrect side / site.

Interpreter Services through Translation Services: Rendering an oral message from one language to another. An interpreter through translation services will use all available knowledge, skills and techniques to provide an accurate and understandable interpretation of all communication between the provider of medical services and the patient. Interpreter Services can also be utilized for deaf patients with an American Sign Language Interpreter.

Official Interpreter: An official Interpreter completes a specialized interpreter-training curriculum and translate communication between the provider and patient.

Telephonic Interpretation: This is when the interpreter is available to interpret through the phone. The patient, family, healthcare provider and interpreter will communicate through phone.

PROCEDURE:

Obtaining Informed Consent

a. It is the treating provider's responsibility to obtain the informed consent. The provider must provide information to the patient about the nature of the procedure, risks, benefits, and alternatives, in a manner that is understandable to the patient so that the patient can make an independent, and voluntary decision whether to proceed with the procedure. The provider will review and discuss the consent form with the patient *prior* to the procedure.
b. The consent form must be completed in the patient's *preferred* language (Creole, Spanish, and English).
   The consent form is not valid if it is not completed in the patient's *preferred* language because the patient lacks the understanding to be able to communicate and ask questions with the provider.
c. If the patients *preferred* language is other than (English, Spanish, or Creole). The provider must utilize the official Interpreter Services through the Language Line: Pacific Interpreters 1.866.421.3463. An access code is required to utilize Language line and can be obtained by your clinical site leader. This access code will be different for each of the HWCOM locations.
d. Present the ***Language Identification Guide*** to the patient.
   The guide of different languages link: https://www.languageline.com/resources/language-lists
e. Inform the patient that Interpreter services will be provided to them at no cost to assist with the translation of the informed consent.

f. **Procedure for languages other than Creole, Spanish, English**. Contact Pacific Interpreters read them a copy of the English Consent that includes all the information pertinent to the procedure (i.e. name of procedure, risks) and they will translate the information through the language telephone line. The patient will sign the English version of the consent form, as well as the provider and the witness. A note will be placed in the EMR that states the Language Line in the patient's preferred language officially translated the English version of the consent. Include the full name of the Interpreter and user ID# and the language line utilized for translation services.
Example: The patient signed the English version of the consent that was officially translated in Mandarin by the interpreter Jane Doe through Pacific Interpreters.

For additional details, see HWCOM Administrative Policy: *Interpreter Services through the Language Line No.:* (Policy under revision)

Completion of the Consent Form

- No abbreviations and the actual naming of the procedure should be spelled out to avoid confusion and prevent procedural errors. Clearly identify which side/ site will have the procedure done.
  Example:
  L elbow I & D (Incorrect, use of abbreviations on the consent form)
  Left elbow incision and drainage (correct)
- List all risks related to the procedure on the consent form
- Patient, provider and witness signature required
- Scan the signed consent in the patients *preferred* language in the EMR (Electronic Medical Record). In addition, scan a blank English unsigned consent in the EMR to have an official translation of the signed consent form.

Exceptions to Completing an Informed Consent:

a. Certain recognized exceptions to informed consent include:
   i. Patient's lack of capacity to consent
      1) If patient is incapable or lacks the capacity to give a consent, a suitable alternative is acceptable, including use of legal guardian or surrogate.
   ii. Minor
      1) If the patient is under eighteen years of age, consent should be obtained and documented from the minor's parent or legal guardian.
b. The facts and reasons for any exceptions should be documented in the EMR.

Contact the Department of Risk/Legal Department if you have any questions regarding patient capacity/ minors or any other questions regarding the informed consent process at 305-348-9174.

Informed Consent for Continuing Therapy

c. Informed consent is obtained before each new treatment or procedure. However, patients in certain therapeutic programs involving a course of multiple treatments may consent to an entire course of routine therapy prior to the first treatment, and a single consent form may be signed for the entire course of treatment if:
   i. The entire course of treatment is disclosed, consented to, and documented in accordance with this policy.

ii. No material change occurs in:
    1) The risks, benefits of and alternatives to the treatment:
        a) The mode of treatment.
        b) The patient's medical condition.
            i) The patient's capacity to consent; and patient does not revoke consent, and consent is re-obtained and re-documented at least annually.
iii. Example of continuing therapy covered by this exception includes Transcranial Magnetic Stimulation (TMS). One consent form is completed for the duration of all the treatment visits.

Responsibility

d. Treating Provider:
    i. Disclose all information relevant to the patient's decision and obtain the patient's informed consent.
e. LPN, CMA, Paramedic:
    i. Verify with the patient or by specific documentation of informed consent in the EMR that the consent has been obtained by the provider prior to the treatment or procedure.
    ii. In the event the nurse determines that informed consent has not been obtained or documented, the nurse will notify the provider who will complete the consent process, speak with the patient, and/or provide specific documentation of the informed process, which has previously taken place.

Incident Reports are completed for the following adverse events, which includes but are not limited to:

- Failure to obtain an Informed Consent
- Provider delegates Informed consent to staff members
- Interpreter services not utilized for informed consent when warranted as described above
- Any additional event deemed appropriate by the reporter

For additional details please see HWCOM Administrative Policy: *Incident Reporting No.:* **200.03.100A**

SUPPORTING/REFERENCE DOCUMENTATION:

- TJC (The Joint Commission), *Quick Safety*. Issue 21, February 2016.
- https://www.jointcommission.org/informed_consent_process_training.aspx
- HWCOM Guide: Examples of Treatments Requiring Written Informed Consent

RELATED POLICIES, PROCEDURES, AND ASSOCIATED FORMS:

- FIU Health General Consent for Medical and Surgical Procedures
- HWCOM Administrative Policy: *Incident Reporting No.:* **200.03.100A**
- HWCOM Departmental Policy: *Universal Protocol*- Time Out No.: **200.02.106P**
- HWCOM Administrative Policy*: Interpreter Services Through the Language Line No.: (Policy under revision)*