GUAM MEMORIAL HOSPITAL AUTHORITY
ADMINISTRATIVE MANUAL

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Joseph Verga, MS, FACHE Hospital Administrator/CEO	Nursing Services Medical Staff Risk Management	04/2013	A-RI300	1 of 8
TITLE: INFORMED CONSENT PROCESS				
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PURPOSE:

To provide information necessary to obtain and document informed consent from a patient/surrogate decision maker in advance of all medical/surgical interventions.

POLICY:

The Guam Memorial Hospital Authority (GMHA) respects the informed consent process by which the competent patient or his/her surrogate decision maker exercises self-determination about the patient's healthcare. The goal of the informed consent process is for the person to understand information relevant to the decision, alternatives and their consequences, and allow the person to freely choose to accept or reject the recommended treatment. This process is grounded in the ethical and legal principles of patient autonomy. The law does not allow a health care provider to substitute his/her judgment for that of the patient in the matter of consent. Therefore, interventions that require informed consent shall not be performed on a patient until informed consent of the patient/surrogate decision maker is obtained, except in an emergency or when court ordered.

DEFINITIONS:

Informed Consent: A process accomplished by a dialogue between the clinician and patient/surrogate decision makers during which the patient/surrogate decision maker is given information and an opportunity to ask questions. The dialogue culminates in the understanding by the patient/surrogate decision maker of the risks, benefits, and alternatives to the procedure under discussion and leads to a decision by the patient/surrogate decision maker.

There are three (3) components of Informed Consent:

1. Competence – the individual must have the capacity to either give or withhold their consent;
2. Sufficient Information - that capacity must be exercised on the basis of sufficient information;
3. Voluntary Choice – the process must be conducted in the absence of coercion so the individual can make a voluntary choice.

Surrogate Decision Maker: The parent/guardian of a minor child (under the age of 18 years); closest relative of an adult patient lacking decision making capacity; the legal proxy designated in a Health or Medical Power of Attorney; or the court appointed guardian of a judicially declared incompetent patient.

Health or Medical Power of Attorney: A legal form that allows an individual to empower another with decisions regarding his/her healthcare and medical treatment. A health or medical power of attorney becomes active when a patient is unable to make decisions or consciously communicate intentions regarding his/her healthcare and medical treatment.

Incompetent Person: An incompetent person includes minors under the age of 18 years, an incapacitated person who exhibits symptoms of remaining incapacitated, or a person found legally incompetent by a court whether due to mental illness or pursuant to 10 GCA §3801.

If a person who suffers from a mental illness, disability or other medical condition that makes him/her incapable of making decisions that affect his/her health and general welfare is identified by a physician or mental health professional, but there are legal documents or information declaring said person mentally incompetent, GMHA will identify that person as "potentially being incompetent" until a court finds him or her legally "incompetent".

GUIDELINES:

I. WHEN INFORMED CONSENT IS REQUIRED IN WRITING

Examples of interventions requiring written informed consent are listed in Appendix A (this list is not all-inclusive).

II. EXCEPTIONS TO WRITTEN INFORMED CONSENT

A. Emergencies

Emergency treatment may be provided to preserve a patient's life or health. However, this emergency exception does not apply if the patient has previously made clearly known that he/she does not want to receive the proposed emergency treatment under the present circumstances. The facts which make the situation an emergency must be documented in the patient's medical record. Emergency treatment under this exception may continue until the patient gains decision-making capacity, or until the patient's surrogate decision maker is available to make decisions on the patient's behalf, at which time informed consent must be obtained from the patient/surrogate decision maker.

B. Court Order

Court ordered treatment may be provided to an individual without consent and despite a patient/surrogate decision maker's objection. The court order authorizing treatment must be documented in the patient's medical record, and a copy of the court order must be placed in the patient's chart.

III. WHO CAN GIVE INFORMED CONSENT

A. A competent adult or emancipated minor can consent or reject treatment unless they lack capacity to do so.

1. In general, a person lacks capacity to give informed consent if he/she:

   (a) does not demonstrate a general awareness of his/her situation and the treatment being proposed;
   (b) cannot understand the factual information provided about the proposed treatment, especially its risks and benefits; OR
   (c) cannot communicate – verbally or nonverbally – a clear decision regarding the proposed treatment based on that information.

2. Clinicians must assess a patient's capacity during each informed consent dialogue and the determination regarding capacity, or lack of, must be documented in the patient's medical record.

NOTE: Disagreement with the recommendation of a health care professional is not evidence of patient incapacity. Clinicians must obtain consent before implementing any proposed treatment.

B. A surrogate decision maker (see definition above). Note that a minor female patient – regardless of age – may provide consent for herself for procedures related to pregnancy or childbirth.

C. If a patient lacks capacity and has not designated a surrogate decision maker, GMHA will meet with the patient's family to determine the identity of the appropriate surrogate decision maker for the patient. If necessary, GMHA will seek assistance from social services (including the Office of the Public Guardian) to obtain court determination and that legal representation be provided for the patient.

IV. INFORMATION THAT MUST BE PROVIDED TO THE PATIENT DURING THE INFORMED CONSENT DIALOGUE

A. The Informed Consent dialogue must be in a language and means of communication that the patient/surrogate decision maker can understand. (Interpreters should be utilized if necessary.) The clinician must ensure that the patient/surrogate decision maker understand the information provided by avoiding technical jargon, asking the patient whether he/she understands, encouraging questions, and/or using the "teach back" method. When using the "teach back" method, the clinician would ask the patient to restate what he/she understands to be the nature and risks of the proposed procedure.

B. It is the hospital's responsibility to ensure that through the informed consent process the patient/surrogate decision maker is provided with all necessary information regarding the patient's health status, diagnosis and prognosis.

C. The clinician's signature on the informed consent form/note in the patient's medical record certifies that the following information was provided:

1. The indications for the proposed surgery or other invasive procedure;

2. A description of the proposed surgery or other invasive procedure, including the anesthesia that will be utilized;

3. Material risks, benefits and side effects for the patient related to the proposed surgery or other invasive procedure and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but a very high degree of severity. A relatively minor risk may be significant to a particular patient. If the clinician knows that the risk would be important to the patient's decision making, the clinician should discuss the risk with the patient;

4. Treatment alternatives, including the attendant material risks, benefits and side effects;

5. The probable consequences of declining recommended or alternative therapies;

6. Who will conduct the surgical interventions and administer the anesthesia, if known;

7. Whether physicians other than the operating practitioner will be performing important tasks related to the surgery or other invasive procedure, in accordance with the hospital's policies.

Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines;

8. The likelihood of the patient achieving his/her goals;

9. Any potential problems that might occur during recuperation; and

10. Any circumstances under which information about the patient must be disclosed or reported.

V. CONSENT FORM

A. Purpose of the Informed Consent Form

1. The purpose of the informed consent form is to verify and document that the *process* of informed consent has occurred between the clinician and patient/surrogate decision maker. Signing the form should be the **last step** in this process.

2. A properly executed consent form must be placed in the patient's medical record prior to a proposed surgery or a procedure, except in the case of emergency or court order.

B. Required Contents

1. An informed consent form, in order to be properly executed, must be consistent with hospital policies as well as applicable Federal and local laws and regulations. The following is a list of items that must be included on each consent form:

   a. Name of the patient and, when appropriate, the patient's representative/surrogate decision maker;

   b. Name of the hospital where the procedure or other type of medical treatment is to take place;

   c. Name of the specific procedure, or other type of medical treatment, for which consent is being given;

   d. Name of the responsible practitioner who is performing the procedure or administering the medical treatment;

   e. Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative;

   f. Signature of the patient or the patient's legal representative; and

   g. Date and time the informed-consent form was signed by the patient or the patient's legal representative.

   h. Name of the practitioner who conducted the informed-consent discussion with the patient or the patient's representative;

   i. Date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form;

j. Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient's representative;

k. Statement, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner; and

l. Statement, if applicable, that qualified medical practitioners who are not physicians but who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under local law and regulation, and for which they have been granted privileges by the hospital.

VI. SCOPE OF INFORMED CONSENT

A. The scope of a patient's consent depends on what the clinician has discussed and what the patient/surrogate decision maker has consented to. A patient may consent to a one-time treatment or procedure (e.g., colonoscopy), routine care of a particular condition that may include a variety of discrete procedures or treatments, or for a series of the same treatment (e.g., dialysis or blood transfusions during a hospital stay).

B. The patient can rescind consent **at any time**, especially when the scope covers several encounters.

C. Sometimes several discrete procedures are ordered and administered by more than one physician (e.g., anesthesia before surgery, blood transfusion not related to surgery). In such a case, clinicians may obtain informed consent from the patient/surrogate decision maker for the respective procedures on a single form.

1. If a single form is used, **each** clinician must certify by his/her signature that the pertinent information for each procedure was discussed with the patient/surrogate decision maker.

D. Clinicians should make certain to utilize the correct informed consent form. Note that the informed consent form for surgery or other invasive procedures does not include the necessary informed consent required for research.

RESPONSIBILITIES:

A. Obtaining informed consent is the clinician's responsibility and cannot be delegated to anyone else. A physician's legal and ethical obligations allow him/her to administer a medical treatment or procedure to a patient only if the patient/surrogate decision maker has given the clinician informed consent to the treatment or procedure.

B. The physician who performs or orders the treatment or procedure is personally responsible for **ensuring and certifying** in the record that the informed consent process has taken place and that the patient/surrogate decision maker has consented to the treatment or procedure, except in cases of emergency or court order.

C. Generally, the responsible physician is the one performing the procedure. In cases where other practitioners actually perform the procedure, the responsible physician is the one who supervises or orders the procedure/treatment. A physician may collaborate with other practitioners who assist in this process; however, **it is the ordering, administering, or supervising physician that is responsible for obtaining the patient's/surrogate decision maker's informed consent and certifying by his/her signature that the informed consent process has occurred.**

PROCEDURE:

I. DOCUMENTATION

A. When written consent is required, the clinician and patient/surrogate decision maker must certify that the informed consent process has occurred, and that the patient/surrogate decision maker is consenting to the procedure or treatment by signing the informed consent form. The signed form must be placed in the patient medical record.

1. Clinician's Signature – As a rule, the clinician must sign the informed consent form before the hospital will permit the proposed procedure to be performed. If the procedure is ordered by the clinician but is administered by a non-clinician (e.g., a blood transfusion or insertion of a central line) and clinician cannot be physically present to sign the form prior the procedure, the clinician may verify that the informed consent conversation took place and that the patient consented.

2. Witness Verification of a Patient's Signature – a hospital employee should verify that the signature on the informed consent form belongs to the patient. However, it is not necessary for the hospital employee to witness personally the informed consent conversation between the clinician and the patient, nor is it necessary for the hospital employee to witness the patient signing the form.

3. Witness to Patient Signing – a hospital employee who observes the patient signing the informed consent form may verify that fact by signing the form as a witness to the patient signing.

B. If the informed consent form is signed by a patient out of a hospital employee's presence, the hospital employee must confirm with the patient that the signature on the form belongs to the patient. The employee must then sign the informed consent form as a witness.

C. If the informed consent form was signed by a patient out of a hospital employee witness's presence but another witness (e.g. a nurse in a clinician's private office) has already signed verifying the patient's signature, the hospital employee may co-sign the form after verifying the patient's signature.

D. When written consent is *not* required, the clinician must still document that the informed consent process has occurred in a progress note to be placed in the patient's medical record. Such note certifies that the clinician has provided the required information to the patient for consideration, and that the patient consents to the procedure. The clinician may – but is not required to – use the informed consent form to guide the discussion of information and document a patient's consent, even when written consent is not required.

II. TIMELINESS

A. Even if there is a delay between when the patient/surrogate decision maker provided his/her consent and when the procedure is performed, the consent will remain valid unless:

1. There has been a significant deviation from the treatment plan to which the patient/surrogate decision maker originally consented, in which case the patient/surrogate decision maker must be informed of and consent to any changes; OR

2. Facts have changed since the clinician's discussion with the patient/surrogate decision maker such that it would be reasonable for the patient/surrogate decision maker to be informed of the change and engage in the informed consent process again; OR

3. The patient rescinded consent, in which case the procedure may not be performed.

B. Even if there has been no significant change, a clinician must discuss the proposed treatment with the patient again if more than thirty (30) days has elapsed between the patient's/surrogate decision maker's consent and the day the procedure will be administered. However, it is not necessary to execute a new consent form if the clinician documents the recent discussion in the patient's record.

ATTACHMENT:

I. **INTERVENTIONS REQUIRING WRITTEN INFORMED CONSENT**

REFERENCES:

Centers for Medicare and Medicaid (CMS) Patients' Rights Condition of Participation 42 CFR 482.13(b)(2)

The Joint Commission (2013). Rights and Responsibilities of the Individual. *Comprehensive Accreditation Manual for Hospitals: The Official Handbook.* Chicago, IL: The Joint Commission.

RESCISSION:

Policy No. A-RI300, *Informed Consent Process,* of the GMHA Administrative Manual made effective December 22, 2009.

ATTACHMENT I

Examples of interventions requiring written informed consent (this list is *not* all-inclusive):

1. Surgical Procedures (not including simple laceration repair or minor dermatological procedures performed in an out-patient setting);
2. Experimental procedures or treatments;
3. Abortions;
4. Administration of blood or blood products (if unrelated to invasive/surgical procedures for which informed consent has already been obtained);
5. Neuroleptic medication when prescribed for the treatment of mental illness or mental retardation (but not when prescribed for other purposes);
6. Any medical treatment necessary to preserve the life or health of a patient;
7. Radiation therapy;
8. Invasive medical imaging;
9. Procedures involving moderate to deep sedation where there is a risk of loss of protective reflexes (Note that a separate anesthesia-specific consent form is required);
10. Circumcisions;
11. Sterilization (Federal and local regulations require additional documentation for consent for sterilization);
12. Surgical or other invasive procedures are those involving a skin incision or puncture including, but not limited to: open surgical procedures, percutaneous aspiration, selected injections, biopsy, percutaneous cardiac and vascular diagnostic or interventional procedures, laparoscopies, endoscopies, and excluding venipuncture or intravenous therapy. Specific examples of other invasive procedures for which written informed consent is required are as follows:

    a. Injections of any substances into a joint space or body cavity;
    b. Percutaneous aspiration of body fluids through the skin (e.g., arthrocentesis, lumbar puncture, paracentesis, thoracentesis, suprapubic catherization);
    c. Biopsy (e.g., breast, liver, muscle, kidney, genitourinary, prostate, bladder, skin);
    d. Cardiac procedures (e.g. cardiac catheterization, cardiac pacemaker implantation, angioplasty, stent implantation, intra-aortic balloon catheter insertion);
    e. Central vascular access device insertion (e.g. Swan-Ganz catheter, percutaneous intravascular catheter (PIC) lines, Hickman catheter);
    f. Electrocautery of skin lesion;
    g. Endoscopy (e.g. colonoscopy, bronschoscopy, esophagogastric endoscopy, cystoscopy, Percutaneous Endoscopic Gastrostomy (PEG), and J-tube placements, nephrostomy tube placements);
    h. Laparoscopic surgical procedures (e.g. laparoscopic cholecystectomy, laparoscopic nephrectomy);
    i. Invasive radiology procedures (e.g. angiography, angioplasty, percutaneous biopsy);
    j. Laser therapy (e.g. eye, ear, nose and throat (EENT));
    k. Dermatology Procedures (biopsy, excision and deep cryotherapy for malignant lesions – excluding cryotherapy for benign lesions;
    l. Invasive ophthalmic procedures;
    m. Oral surgical procedures including tooth extraction and gingival biopsy;
    n. Skin or wound debridement performed in the operating room; and
    o. Renal dialysis.

GUAM MEMORIAL HOSPITAL AUTHORITY
REVIEW AND ENDORSEMENT CERTIFICATION

The signatories on this document acknowledge that they have reviewed and approved the following:

□ Bylaws — Submitted by Department/Committee: **Nursing Management Committee**

□ Rules & Regulations — Policy No.: **A-RI300**

■ Policies & Procedures — Title: **INFORMED CONSENT PROCESS**

Reviewed/Endorsed	**Date**	**Signature**
	08/15/2012	
Title	**Christine Tuquero** **Assistant Administrator of Nursing Services, Acting**	
Reviewed/Endorsed	**Date**	**Signature**
	10/10/12	
Title	**Steven Baacke** **Patient Safety Committee, Chair**	
Reviewed/Endorsed	**Date**	**Signature**
	10/24/12	
Title	**Jonathan Sidell, MD** **Medical Executive Committee, President**	
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	4/4/13	
Title	**Joseph Verga, MS, FACHE** **Executive Management Committee, Chair**	
Reviewed/Endorsed	**Date**	**Signature**
	4/30/13	
Title	James Stadler, MD Ethics Committee, Chairperson	
Reviewed/Endorsed	**Date**	**Signature**
Title		
Reviewed/Endorsed	**Date**	**Signature**
Title		

***Use more forms if necessary. All participating departments/committees in developing the policy should provide signature for certification prior to submitting to the Compliance Officer.**