HACKETTSTOWN REGIONAL MEDICAL CENTER
ADMINISTRATIVE POLICY MANUAL

CONSENT

Effective Date:	**07/1993**	**Policy No:**	**AD36B**
Cross Referenced:		**Origin:**	**Patient Care**
Reviewed Date:	**11/2010**	**Authority:**	**Chief Medical Officer**
Revised Date:	**11/2010**	**Page:**	**1 of 13**

SCOPE

All departments within Hackettstown Regional Medical Center

PURPOSE

- To establish guidelines for obtaining both general and informed consent for medical intervention;
- To recognize the right of each individual to fully participate in his/her health care decisions through the informed decision making process;
- To outline circumstances when a surrogate decision maker, rather than the patient, may give informed consent or when care, treatment, and services normally requiring informed consent may be given without informed consent.

DEFINITIONS

Autonomy: Autonomy is "self-rule" by the patient that "every human being of adult years and who possesses decision making capacity has a right to determine what will be done with his/her own body." An autonomous choice is one that is made intentionally, with understanding and without controlling influences. The autonomous patient acts in accordance with a freely self-chosen and informed plan.

Mentally Incompetent/Disabled: A mentally incompetent or disabled patient is one that is incapable of making an informed decision regarding treatment.

Informed Consent: Informed consent is a process that culminates in the final authorization by a patient, or a patient's surrogate decision maker, for a proposed medical intervention. This process can be divided into five elements: competence, disclosure, understanding, voluntariness, and authorization.

General Consent: General consent differs from informed consent in that there are no risks, benefits, alternatives to treatment, and/or possible problems to recuperation disclosed. The general consent allows for the provision of non invasive examinations, diagnostic radiology, therapeutic intervention such as medication administration, rehabilitation, blood specimens, IV insertion etc., which occur in the general course of care, treatment, or services.

Competence or Decision Making Capacity: Competence is a precondition for making an autonomous decision. It is the ability of an adult patient to understand the nature, extent and probable consequences of a proposed treatment, to make a rational evaluation of the burdens, risks and benefits of a treatment and to communicate his/her decision. A patient might possibly be judged competent to make an informed decision regarding a simple, low-risk intervention but not a more complex or higher risk intervention. A patient might also be competent at one point in time but not at another, e.g. because of drug effects or acute illness.

Disclosure: Disclosure involves informing the patient at an appropriate time prior to a treatment or procedure, the exact nature of that treatment or procedure in terms that the patient can understand. This information should include (1) those facts or descriptions that patients usually consider material in deciding whether to refuse or consent to the proposed intervention, (2) information the physician or care-giver believes to be material, (3) the physician's recommendation and (4) the purpose of seeking the patient's authorization. More specifically, information provided should include a discussion of the prognosis with and without the proposed intervention and the fact that satisfactory results are not guaranteed, common risks of the procedure as well as risks and side effects of proposed medications, alternative treatments and medications and the possible consequences of the patient's refusal of treatment. Disclosure should also reflect that individual(s) other than the surgeon(s) already listed on the consent may be performing significant surgical task(s). Significant surgical tasks include, but are not limited to: suturing, stapling, opening and closing, harvesting of grafts, dissecting tissue, removing tissue, and implanting devices (such as PICC lines).

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Understanding: The physician or care-provider must give the patient opportunity to understand the content and implications of the disclosed information. The information must be provided in a form comprehended by the patient, especially information relating to risks and complications. A language interpreter or special assistance may be necessary to communicate effectively with a patient who cannot hear, speak or read English. Questioning the patient's understanding, discussing the proposed intervention on more than one occasion, including family or close friends in discussions and discussing a patient's possible misperceptions of disease or risks of treatment may be necessary in order to determine adequate understanding of the disclosed material.

Voluntariness: If a patient is to make a truly autonomous decision, he/she must make it voluntarily and should not be unduly influenced by external factors. The patient's authorization of an intervention must be made in the absence of coercion, manipulation or forceful persuasion. The physician should attempt to alleviate subtle intimidating factors.

Authorization: The final step in the process of informed consent is the authorization by the patient for a proposed intervention. This authorization is valid only if the patient is acting autonomously. If the patient chooses to authorize the proposed intervention, the authorization is formalized by the patient reading, amending and signing the Consent for Operative, Other Invasive, and Non-Invasive Procedures and Anesthetics. Authorization is revocable and a patient's decision regarding authorization may be changed at any time. Witnesses to the authorization are attesting only to the patient's signature and are not verifying that the patient has been properly informed or that he/she is competent to refuse or consent to treatment.

Health Care Decision: A health care decision means a decision to accept or to refuse any treatment, service of procedure used to diagnose, treat, or care for a patient's physical or mental condition, including life-sustaining treatment. Health care decision also means a decision to accept or to refuse the services of a particular physician, nurse, other health care professional, or health care institution, including a decision to accept or to refuse a transfer of care.

Physician: Physician means an individual licensed to practice medicine by the New Jersey Board of Medical Examiners, and where specifically indicated in this policy, may include an allied health practitioner acting within the area of his/her practice (i.e., nurse anesthetist, nurse midwife) to the extent the allied health practitioner has the knowledge necessary to discuss the risks, benefits and alternatives to a procedure requiring informed consent.

Minor: Individuals who are under 18 years of age.

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POLICY

I. It is the right of every patient or his/her surrogate decision maker (as described in Section V), in collaboration with his/her physician, to make informed decisions about medical treatment that reflect his/her wishes.

II. For procedures/treatments that require written authorization (see **Interventions Requiring Consent**, below), the patient and physician need to complete the ***Informed Consent for Operation, Procedure, Test, or Treatment.*** (Form No. H0003962)

III. The physician who is performing the procedure will provide information that the physician, in the exercise of his or her judgment, deems appropriate with regard to the risks of and alternatives to the procedure and/or therapies to the patient in terms understandable to the patient. Thereafter, either the physician or designee will obtain the informed written consent of the patient on a consent form approved by the hospital, for the provision of that specific medical treatment/procedure before the procedure/service is begun. Physician confirmation of informed consent must be documented before the procedure/service is begun, by completing the designated section of the ***Informed Consent for Operation, Procedure, Test, or Treatment.*** (Form No. H0003962)

IV. If a patient or his/her surrogate decision maker is able to understand procedures, absorb facts, and make a valid judgment, then he/she is the only one who may give consent. The patient has the responsibility of being an active partner in his/her care planning process. If the patient is temporarily unable to give consent due to sedation, etc., and the circumstances do not call for immediate treatment, the action should be delayed until the patient can make a judgment about the course of treatment. Spouses and family members cannot sign for consent if the patient is mentally capable to do so except in emergency life-threatening conditions.

V. It will be the responsibility of the physician to determine that the appropriate consent forms have been completed, signed and witnessed, before any medical/surgical/invasive treatments/procedures that may involve an element of risk, are begun.

VI. A patient with decision making capacity has the right to refuse medical treatment after the informed consent process of disclosure has taken place. It is particularly important when a patient is refusing medically indicated treatment to fully and thoroughly explain to the patient the risks of his or her decision and to obtain a psychiatric consultation if there is any doubt as to the patient's decision making capacity to refuse treatment.

VI. In life-saving emergencies, where a delay in obtaining informed consent may be detrimental to the patient, the process of informed consent may be waived. In these cases, the physician shall document existence of the life-threatening emergency in the medical record.

VII. This policy does not give the patient the right to demand treatment or services which the physician deems medically unnecessary or inappropriate. In the event of a disagreement between the patient or surrogate decision maker and the physician, resources include the Social Service Department, the Ethics Committee, or the Administrator on Call.

VIII. The disclosure discussion between patient and physician should also include a discussion regarding any non hospital staff that may be present during the procedure and in what capacity such staff will be present.

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PROCEDURE

I. OBTAINING GENERAL CONSENT

A. General consent differs from informed consent in that there are no risks, benefits, alternatives to treatment, and/or possible problems to recuperation to be disclosed. The general consent allows for the provision of non invasive examinations, diagnostic radiology, therapeutic intervention such as medication administration, rehabilitation, blood specimens, IV insertion etc., which occur in the general course of care/treatment. The general consent for treatment allows for basic examination, consults, and non invasive treatment, care or service to be provided.

B. Every effort must be made to obtain the general consent directly from the patient. For example: if a patient is having a test and requires a general consent for admission, wait until the patient is available to sign his/her own consent. If the patient's writing ability is hampered, encourage use of the alternate hand for signing or obtain verbal consent from the patient.

C. Only if the patient is unable to consent due to a clinical condition or age (i.e. , a minor), may a surrogate decision maker give a general consent.

D. If verbal consent is obtained, it should be done in the presence of two (2) staff members to serve as witnesses to the verbal consent. Any verbal authorization must be indicated on the general consent.

E. If a general consent for treatment cannot be obtained at the time of admission (i.e., patient condition, availability of family), it is the responsibility of the Registrar to follow up with an attempt to have the patient sign when medically able or to contact a surrogate decision maker to provide general consent.

F. It is encouraged that general consent be obtained in person, whenever possible, when given by a surrogate decision maker. However, if that is not possible, telephone consent may be accepted for general consent. Two (2) staff members must listen to the telephone consent, indicate who is giving consent, relationship to patient, reason patient cannot consent, and the date and time consent is obtained, and both will serve as witnesses.

G. General consents must include the date, time, relationship of signatory (e.g., self, mother, spouse, legal guardian), reason for alternate signature if other than the patient (e.g., condition, minor) and a witness signature to the signing process.

II. OBTAINING INFORMED CONSENT

A. The physician providing the service is to provide the necessary information and explanation to the patient or his/her representative, in terms the patient/representative can understand, and to obtain the patient's signature. The physician, by virtue of education and training, has the knowledge to disclose information about the nature of the proposed care, treatment, medication, intervention, or procedure, its potential risks, expected benefits, side effects (including potential complication(s) that might occur during recuperation), and any viable alternatives. The physician rendering the care will also inform the patient/representative of the likelihood of achieving the goals associated with the care/treatment, the relevant risks, benefits, and side effects related to alternatives, including the possible results of not receiving care or treatment. The need for blood or blood components, the risks and alternatives to transfusion are also considered. This knowledge is extended to the nurse

anesthetists for anesthesia administration, nurse midwives for obstetrical care and/or vaginal delivery and nurse practitioners with prescriptive authority for medications that require informed consent.

B. If the patient still has questions at any time before the treatment about the treatment / procedure, the process will be stopped and the physician informed so the patient can be fully clear on the issues before signing the form.

C. The physician (as defined in this policy) must discuss the elements of informed consent in such a way that the patient/surrogate decision maker understands the patient's condition and the proposed procedure and is able to appreciate the significance of what is being explained (in layman's terms). The discussion between the physician and patient or surrogate decision maker as part of the informed consent process must include: (i) a description of the patient's condition and the proposed procedure, including anesthesia to be used, and the nature and purpose of such to patient; (ii) potential benefits of the proposed procedure to the patient; (iii) potential short and longer term risks, or side effects, including potential problems that might occur during recuperation; (iv) a description of the risks and benefits based on available clinical evidence.

III. COMPLETING AND SIGNING THE CONSENT FORM

A. It is the responsibility of the physician providing the procedure to discuss the elements of informed consent with the patient and/or surrogate decision maker. The informed consent process is documented with the patient and/or surrogate decision maker. The informed consent process is documented on a consent form which must be completed by the physician. The informed consent form must be placed in the medical record prior to the procedure.

B. It is preferred that the consent form be signed by the patient or the surrogate decision maker at the time the procedure is explained by the physician. It must be signed before the procedure is performed on the patient, except in an emergency.

C. Staff shall serve as witness to the signature only and are not to discuss/explain the contents of the informed consent. All questions must be referred to the physician.

D. A properly executed informed consent form must contain at least the following:

a) Name of the patient, and when appropriate, the patient's surrogate decision maker;
b) The patient ID label
c) Where the procedure will take place;
d) Name of procedure for which informed consent is being given;
e) Name of responsible practitioner(s) performing the procedure(s)
f) Statement that the procedure, including the anticipated benefits, risks and alternative therapies, were explained to the patient or the patient's surrogate decision maker prior to the procedure;
g) A description of the procedure;
h) Signature of patient or surrogate decision maker (with relationship);
i) Date and time the consent is obtained from the patient or surrogate decision maker; and date, time and signature of the professional person witnessing the consent. Obtain the patient's signature or surrogate decision maker's signature only after this information is on the informed consent document.

E. Although the written informed consent does not need to specify the following, according to CMS

guidelines, discussing the following elements during the physician-patient disclosure as part of the informed consent decision making process is considered good practice. Therefore, the following procedure should be followed:

a) The patient shall be notified if physicians other than the operating practitioner may perform important tasks related to surgery in accordance with hospital policy. Important surgical tasks may include opening and closing, dissecting tissue, removing tissue, harvesting graphs, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines.

b) Discussion should include whether, as permitted by State law, qualified medical practitioners who are not physicians will perform important parts of the surgery or anesthesia, and if so, the types of tasks each type of practitioner will carry out, and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the hospital.

F. Abbreviations are not permissible. Entries should be printed.

G. If an error is made while completing the form, corrections must conform to the standards of the Medical Record Department.

H. Multiple treatments/procedures scheduled for the same day may be included in a single consent form provided:
   a) The treatments/procedures are related and;
   b) They are to be performed by the same physician; and
   c) The physician has explained all treatments/procedures to the patient beforehand. If not, then separate consent forms must be executed.

I. If any additions or corrections are made to the consent form after the patient/surrogate has already signed, the additions or correction will be dated, timed and initialed by the patient/surrogate.

J. The patient will sign the consent form only after the physician has completed the informed consent process and the patient has had the opportunity to ask questions.

K. If the services of an interpreter are used during the consent procedure, the name of the interpreter will be documented in any available space on the back page of the consent, along with the interpreter's ID number (when applicable), the date and time the interpretation took place and the interpreter will sign the entry. For telephone interpretation, the name of the interpreter, the interpreter's ID number, the date and time the interpretation took place and "Interpretation via CyraCom (brand name of phone service)" or similar notation will be documented and the transcriber will sign their name.

L. A Spanish version of the ***Informed Consent for Operation, Procedure, Test, or Treatment*** is available for distribution to Spanish speaking patients <u>for reading purposes only.</u> When a Spanish consent is provided to the patient to read, this information will be documented in any available space on the back page of the English consent form. The English version of the consent will be completed, signed and witnessed for all patients undergoing surgery/ procedures.

M. The consent form will be completed and signed before the patient's pre-operative medication is given, and before the patient is taken into the procedure room.

IV. CONSENT BY OR FOR A MINOR

A. **Patient is a minor**: Informed consent for all patients under the age of eighteen (18) must be signed by at least one (1) parent or legal guardian(s), who have legal custody of the child, following the same principles outlined in the General Consent policy. Despite this, the minor has the same capacity to consent to medical treatment as an adult if one or more of the following apply:

a) Married Person: By law, a married person who is a minor or a pregnant woman who is a minor may consent to medical or surgical care on his/her behalf or on behalf of any of his/her children. For such purposes, a married person who is a minor or a pregnant woman who is a minor is deemed to have the same legal capacity to act and to have the same powers and obligations as a person of legal age.

b) Venereal Disease: A minor may consent to medical or surgical care or services by a hospital, clinic or physician when the minor is or believes to be afflicted with a venereal disease.

c) HIV/AIDS: a minor is at least 13 years old and is, or believes that he/she may be infected by HIV or have acquired AIDS may consent to his/her medical services.

d) Sexual Assault: In the case of a minor who has been sexually assaulted, the minor may consent to his/her treatment as if he/she has reached the age of majority. In the case of a minor who appears to have been sexually assaulted, the minor's parents or guardian shall be notified immediately unless the attending physician believes that it is in the best interest of the minor not to do so. The inability of the hospital, physician or clinic to locate the parents or guardian shall not preclude the rendering of any necessary emergency medical or surgical care to the minor.

e) Drug/Alcohol Treatment: In the case where a minor believes that he/she is suffering from the use of drugs or is a drug dependent person as defined in N.J.S.A 24:21-2 and, or is suffering from alcohol dependence or is an alcoholic as defined in N.J.S.A. 26:2B-8, his/her consent to treatment under the supervision of a physician licensed to practice medicine, or an individual licensed or certified to provide treatment for alcoholism or in a facility licensed by the State to provide for treatment of alcoholism shall be valid and binding as if the minor had reached the age of majority. Treatment for drug use, drug abuse, alcohol use or alcohol abuse that is consented to by a minor shall be considered confidential information, and neither the minor nor the physician, hospital or hospital personnel shall be required to report such treatment when it is the result of voluntary consent, except as may otherwise be required by law. The consent of no other person (including but not limited to a spouse, parent, custodian or guardian) shall be necessary in order to authorize such services to be provided by a physician licensed to practice medicine or by an individual licensed or certified to provide treatment for alcoholism.

f) Voluntary Psychiatric Treatment: A minor age 14 or over who requests admission to an institution for voluntary psychiatric treatment is able to consent to his/her admission provided that the court, on a finding that the minor's request was voluntary, enters an order approving the admission. Psychiatric Emergency Screening Services (P.E.S.S.) will determine the need for parental, Division of Youth and Family Services (DYFS) or court intervention. If there is a court order approving a voluntary admission of a minor, the minor may discharge himself or herself in the same manner as an adult. N.J.A.C.10:7-2.1.

g) Unmarried Minors with Divorced Parents: Unless a parent's right to consent has been terminated as specifically determined through the production of a Court Order, either parent may consent to medical or surgical treatment of a minor child. If there is a conflict as to treating the child, the decision as to permitting treatment rests with the parent who has been awarded custody. If a disagreement arises between parents regarding who may consent to treatment, a copy of the custody order must be requested. If there is a disagreement between the parents as to whether treatment should be permitted and no written agreement as to the custody exists, treatment should not proceed until the parents agree. An exception to this rule is in the case of an emergency. Contact Risk Management regarding disagreements that cannot be resolved.

h) Unmarried Minor When Parents Are Not Available: This paragraph deals with situations when the child is at school, camp, in the care of a baby sitter, etc. With the exception of emergency action, only the parent or Surrogate Decision Maker may give consent. If the parent or Surrogate Decision Maker has provided a written statement that the person in charge of the child can give consent, it should be accepted as the consent of the parent for routine care and treatment only. Screening exams may be necessary to ensure an emergency medical condition does not exist.

i) Parental Refusal of Treatment When the "Life or Limb" of a Minor is Jeopardized: If a decision to refuse care will likely result in death of the minor or subject the minor to loss of bodily/mental function, and there is not time to obtain a court order authorizing the necessary treatment, consent is implies and medical caregivers may provide treatment in the best interest of the minor. In emergency circumstances, caregivers my act immediately to prevent such loss
or death. All other circumstances should be referred as soon as practicable to the hospital's Case Management Department, Risk Management or Corporate Counsel.

j) Foster Child: The Division of Youth & Family Services of the appropriate county is to be notified when consent for treatment is needed for a child in foster care.

k) Minor Placed for Adoption: If a child has been released by a parent for adoption, the adoption agency generally has the ability to consent to treatment. The Social Services Department should be consulted for determination of appropriate legal consent.

l) Emancipated Minors: A patient under 18 years of age must be asked to give consent for his or her own treatment if/she is emancipated (e.g., living away from home independent of his or her parents, and/or self-supporting). Proof of a court order for a minor claiming to be emancipated is required. Otherwise, they are treated like any other minor and parental consent is required, or a special medical guardian must be appointed before treatment is provided, except in life threatening situations.

V. DECISIONS FOR THOSE LACKING DECISION MAKING CAPACITY

A. Competent adult patients have the right to make medical decision for themselves. However, if the patient is determined to have lost decision making capacity, the following individuals or classes of individuals, in descending order of priority, may make decisions about health care for a person who has been certified to be incapable of making an informed decision (see certification requirements below):

a) A healthcare agent appointed by the patient under an advance medical directive or durable power of attorney which extends to healthcare decisions (a copy of the document must be submitted by the agent and included in the patient's medical record);
b) A patient's legal guardian when a copy of the court order of guardianship has been submitted by the guardian and included in the patient's medical record;
c) The patient's legal spouse in marriage or civil union;
d) The patient's domestic partner;
e) An adult child of the patient;
f) A parent of the patient;
g) An adult brother or sister of the patient; or
h) Grandchildren, grandparents, aunt/uncles, nieces/nephews or cousins.

Individuals in a particular class may be consulted to make a decision only if all individuals in the next higher class are unavailable. "Unavailable" means that, after reasonable inquiry, the provider is unaware of the existence or the whereabouts of a decision-maker, the decision-maker has not responded in a timely manner (in view of the patient's condition) to the provider's inquiry, or the decision-maker is incapacitated or unwilling to make decisions regarding the patient's care.

NOTE: Guardianship/Proxy Directives and Medical Power of Attorney papers should be requested and a copy placed in the chart. The extent of such person's authority to make decisions may be governed by the designating document and therefore must be carefully reviewed by the attending physician and the patient's Surrogate Decision Maker.

B. Standards for Surrogate Decision Maker

a) All surrogate decision-makers will base those decisions on the wishes of the patient, and if the patient's wishes are unknown or unclear, on the patient's best interest. In determining the wishes of the patient, the surrogate will consider the patient's:
    i. Current diagnosis and prognosis with and without the treatment at issue;
    ii. Expressed preferences regarding the provision of, or the withholding or withdrawal of, the specific treatment at issue or of similar treatments;
    iii. Relevant religious and moral beliefs and personal values;
    iv. Behavior, attitudes, and past conduct with respect to the treatment at issue and medical treatment generally;
    v. Reactions to the provision of, or the withholding or withdrawal of, a similar treatment to another individual; and
    vi. Expressed concerns about the effect on the family or intimate friends of the patient if the treatment were provided, withheld, or withdrawn.
b) The surrogate's decision should not be based, in whole or in part, upon either the patient's pre-existing, long-term mental or physical disability, or a patient's economic disadvantage.
c) The surrogate will inform the patient, to the extent possible, of the proposed procedure and the fact that someone else is authorized to make a decision regarding that procedure.

C. Disputes Among Surrogates

a) In disputes between surrogates in different classes, the decisions of the person in the higher class will prevail, absent a court order or other legal proceedings to the contrary.

b) In disputes between surrogates in the same class, the attending physician or any of the possible surrogate decision-makers identified above may refer the case to the Hospital's Ethics Committee. The attending physician then may act in accordance with the Committee's recommendations or may seek to transfer the patient to another physician and/or hospital.

VI. REFUSAL OF CARE

A. A competent adult generally has the right to decide whether or not he/she wishes to receive medical treatment. If a competent adult patient refuses medical treatment, it is the responsibility of the attending physician (or the nurse if the physician is not reasonably available) to advise the patient of the probable/possible consequences of such a decision. If the decision is not changed, the hospital will not proceed with treatment. Family members of a competent adult patient cannot determine whether or not the patient should receive treatment.

a) When a competent adult patient chooses not to accept medical attention in a life-threatening situation, but has minor dependents who need the patient to provide for their daily support, social work should be contacted to counsel the patient to the extent practicable.

b) A relative or friend cannot refuse treatment for an incapacitated patient if the lack of treatment will result in serious bodily harm, permanent injury or death, unless the relative/friend has been appointed as the patient's agent under an advance medical directive, the relative has obtained a court order, or the refusal of treatment is otherwise authorized under New Jersey law.

c) A parent or legal guardian cannot refuse treatment for a minor child when the minor child is unable to consent on his/her own behalf and faces substantial risk of death or serious or permanent injury, unless the patient is incapacitated and has a terminal illness, end-stage condition, or is in a persistent vegetative state. If the parent(s) refuse consent to treatment and the minor patient faces substantial risk of death or serious or permanent injury, a court order is to be sought through hospital counsel.

d) A competent adult patient may refuse treatment by advising his/her physician of his/her choice, or if the patient is incompetent, through the use of prior specific instructions to his/her physician or of an advance medical directive.

e) When the attending physician is willing to accept the patient's decision to refuse medical treatment the ***Refusal of Care*** form (Form No. H00010083) may be completed.

VII. TELEPHONE OR FAX CONSENT BY SURROGATE DECISION MAKER

A. Telephone consent of a surrogate decision maker should only be used when a written consent cannot be obtained.

B. The physician should have two licensed clinical professionals; one must be an RN, to witness the informed consent discussion when given by telephone. The licensed staff members must listen to the phone conversation at the same time. The physician should then fully advise the surrogate decision maker regarding the condition of the patient and disclose the elements of informed consent.

C. Ask the person giving informed consent to repeat the discussion with a simple explanation to

ensure that there is an understanding of the disclosure communication.

D. The informed consent of the surrogate decision maker shall be recorded on the consent form and witnessed by both persons hearing the consent given. The name of the individual providing consent, relationship to the patient, and date and time the consent was received, must be documented in the medical record.

E. It is not always possible that the physician discussion of informed consent with a surrogate decision maker is done in the presence of a nurse. In circumstances when the registered nurse does not hear the actual disclosure, two (2) licensed professionals need to verify that the discussion of informed consent took place with the physician and both licensed professionals (one who must be an RN) will serve as witness to the telephone consent.

F. Consents by fax: (Patient incapable of giving consent). Consent by fax are acceptable but must be obtained in the following manner. The physician will advise the surrogate decision maker regarding the patient's condition and will disclose the elements of informed consent. The consent form is then completed by a staff member. The form is faxed to the surrogate decision maker. The surrogate decision maker must sign the consent form and fax it back to the facility and return the signed original to the facility by mail. When the signed original consent form is received by the facility, the nurse should witness the signature indicating that the consent was received by fax. The fax transmittal verification should by attached to the consent.

G. The name and relationship of the individual giving the consent will be verified by the signatures of the hospital representatives.

VIII. REFUSAL TO CONSENT TO TREATMENT BY SURROGATE DECISION MAKER

A. Unlike patients who are making decisions about their own medical treatment, surrogate decision makers do not have an unqualified right to refuse medically indicated treatment for a patient other than for themselves, or to have a patient discharged from the hospital against medical advice, unless the surrogate decision maker is acting in accordance with the patient's specific instructions set forth in an Advance Directive meeting the requirements of New Jersey law. If a surrogate decision maker is refusing medically indicated treatment, Risk Management should be consulted as it may be appropriate to obtain a Court Order authorizing treatment of the patient over the surrogates decision maker's objection under these circumstances.

IX. LENGTH OF TIME CONSENT FORM IS VALID

A. In general, a signed consent should be renewed after the passage of 30 days, or if there is a significant change in the circumstances or factors pertinent to the patient's decision. Whenever such a change occurs, a new informed consent must be obtained. Consents signed prior to hospitalization must meet the requirement of this policy and be forwarded to the facility by the physician prior to the procedure.

B. The signed General Consent is valid for the period of each hospitalization.

C. Special Consents may be obtained once for a series of similar procedures or treatments. As long as there are no changes to the proposed course of procedures/treatment, or changes to the risks, benefits and /or alternative to the proposed procedures/treatment, the original consent will remain valid and no additional consents are required.

D. The patient may also revoke his or her consent at any time. The revocation must be documented in

the patient's medical record, including the date and time, whether the revocation was verbal or in writing, and if verbal, the names of individuals who witnessed the revocation.

E. If multiple procedures have been included on a single consent form (Completing and signing the Consent Form above), and only one is performed, a new consent form will not have to be completed if:

a) The time lapse between the two procedures/treatments does not exceed 24 hours, and
b) The medical circumstances have not changed, and
c) All treatments/procedures will be performed by the same physician.

X. SPECIAL CONSENT CONSIDERATIONS

A. Sterilization: A special consent form and process must be used for patients who wish to undergo sterilization procedures and who are Medicaid or NJ Family Care fee for service beneficiaries,

a) In order to complete the consent form/process, the relevant patient must be at least 21 years of age and can not be mentally incompetent, institutionalized, intoxicated, seeking to obtain or obtaining an abortion, or in labor or childbirth.
b) At least 30 days, but not more that 180 days must pass between the date of the informed consent and the date of the sterilization, except in the case of emergency abdominal surgery or premature delivery. In the case of emergency abdominal surgery at least 72 hours must pass between the date of the informed consent and date of sterilization. In the case of premature delivery, informed consent must have been given at lease 30 days before the expected date of delivery and at least 72 hours must have passed between the date of informed consent and the premature delivery. In the case where a patient desires to be sterilized at the time of delivery, the consent form must be signed by the patient no earlier than the 5th month of pregnancy. N.J.A.C. 10:52-13©.
c) In addition to the other informed consent requirements contained herein, the patient undergoing the sterilization procedures must be informed : (i) that he or she is free to withdraw consent at any time without affecting the right to future care; (ii) of alternative methods of family planning; (iii) that the procedure is considered irreversible; and (iv) that the procedure will not be performed for at least 30 days except as noted above.

B. Research-Related or Experimental Procedures: A special consent form is required before performing research-related or experimental procedures. Prior to any such procedures, the patient shall be informed and appropriate informed consent form obtained.

C. Intoxication: In certain circumstances, law enforcement officials may request that the hospital draw blood from a patient who has not given informed consent in order to determine the patient's level of intoxication. The hospital may be permitted to perform such procedure, provided no unnecessary force is used to obtain the sample. The hospital should attempt to obtain consent from the patient.

XI. INTERVENTIONS REQUIRING CONSENT

A. Interventions requiring use of the ***Informed Consent for Operation, Procedure, Test, or Treatment*** as formal documentation of informed consent and patient authorization include but are not limited to:

a) All surgical or invasive procedures;
b) Any radiological procedure involving intravascular injection of contrast materials or performance of percutaneous biopsy or drainage;

c) Placement of intravascular monitoring catheters, other than as an adjunct to the administration of anesthesia that has been authorized separately;
d) Invasion of body cavities for the purpose of drainage, biopsy or monitoring
e) Endoscopic procedures;
f) Any stress test;
g) Traction pins;
h) Cardioversion (elective).

B. Other treatment decisions requiring documentation of informed consent on a hospital-approved consent form:
a) HIV testing;
b) Chemotherapy;
c) Hemodialysis;
d) Refusal of blood transfusion;
e) Blood Transfusion;
f) Thrombolytics