1.0 POLICY:

Patient and /or his family members are informed on risks benefits, alternatives and as to who will perform the requisite procedure in a language they can understood.

2.0 PURPOSE: -

To define the obligations in obtaining and documenting informed consent by Inodaya Hospitals Kakinada - physicians and staff.

3.0 DEFINITION:

Informed consent is a legal condition whereby a person can be said to have given consent based upon a clear appreciation and understanding of the facts, implications and future consequences of an action. In order to give informed consent, the individual concerned must have adequate reasoning faculties and be in possession of all relevant facts at the time consent is given

4.0 ABBREVIATIONS:

DMS – Director of Medical Services

5.0 SCOPE: All patients who will undergo any surgical procedure and/or any intervention (follow the List of conditions) at INODAYA Hospitals

6.0 RESPONSIBILITY:-Treating Physician

7.0 DISTRIBUTION: All patient care areas

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8.0 PROCESS DETAILS:

8.1 DESCRIPTION OF THE PROCESS
Types of consent:

a. **Implied consent** in Medical Emergency: Consent shall be implied either by words or behavior of the patient or the circumstances under which the treatment is given. Consent in emergencies shall be implied if the condition of the patient precludes his/her ability to make a decision regarding treatment or procedures.

b. **Specific consent** shall be used when the treatment is likely to be more than mildly painful and carries appreciable risk. This type of consent shall be used for all procedures performed in the Main Operation Theatres also for non-routine diagnostic or therapeutic/ invasive procedures and investigations performed in the hospital.

c. **GENERAL CONSENT:** This consent shall be signed by every patient during the admission process and new registration. This is a limited consent, which is part of the basic medical record; this consent of authorization is only for basic investigation, treatment. The scope the general consent shall be explained to the patient/ his family members.

1. It shall be the responsibility of the person obtaining the consent to ensure that the consent form is properly filled and that the patient or the surrogate decision maker has initialed all modification or deletions.

2. A witness shall also sign in the consent form. A witness shall be anybody among family members / friends. A witness signs in agreement that the patient /surrogate decision maker has been given adequate information and fully understood and agrees to the decision taken by the treating doctor/assignee

Consent is to be given by

- The patient, unless he or she is a minor, under effect of alcohol or other sedative drugs, Pregnant women or woman in labor& Unconscious
- If patient is incapable of informed decision making, consent shall be obtained from next of kin / parent / guardian, as per law of the land.
- In situations when there is no consensus amongst children of the patient, they are asked to nominate one of their siblings in writing with signatures of two witnesses. The informed consent is obtained from the nominated person.
- In case of unidentified patient in unconscious condition, treating doctor shall take a decision in life threatening circumstances.
- In life threatening situation, where no next of kin is available the DMS will give permission for the procedures that needs to be done.

The patient's rights:

- Patients must be given information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care.
- A patient has the right to give or withhold consent prior to examination or treatment.
- Patients must be allowed to decide whether they will agree to the treatment and they may refuse treatment or withdraw consent at any time.
- Minors and incompetent adult's rights regarding informed consent will be exercised through their parents or legal representative.
- The physician performing a medical or surgical procedure on a patient is responsible for obtaining the patient's informed consent prior to the treatment or procedure.

Special Instructions:

A. **Elements of Informed Consent**:

- While taking an informed consent, the patient shall be provided with sufficient information so that he/she understands the nature of his/her condition, the nature and purpose of the proposed treatment, the risks and consequences of the procedure or treatment, the feasible alternative procedure or treatment, the

expected outcomes and the consequences if the procedure is not performed nor any treatment given.

- The treating physician and his team member shall discuss in lay terms the procedure, its indications, risks, benefits and alternatives with the patient or the patient's surrogate. The responsible physician or his team member shall document the discussion by obtaining the patient's or his surrogate's written informed consent.
- The priority order of surrogate decision maker shall be spouse, adult children, parents, adult siblings, adult grandchildren, close friend or significant other.
- The patient has the right to know the identity of the treating physician and/or his/her designee responsible for their care
- The doctor shall explain the following while consent taking:
    - the patient's condition;
    - the proposed treatment(s) or procedure(s);
    - the name of the person providing the treatment;
    - potential benefits and drawbacks;
    - possible alternatives;
    - the likelihood of success;
    - possible problems related to recovery; and
    - Possible results of non-treatment.

- The hospital shall provide any other information about the physician, if requested by the patient or family.
- It shall be the responsibility of the person obtaining the consent to ensure that the consent form is properly filled and that the patient or the surrogate decision maker has initialed all modifications or deletions. The date and time of signing shall be clearly indicated.
- A witness shall also sign in the consent form. A witness shall be anybody among family member/friend of the patient; family member/friend of other patients; hospital staff etc. A witness signs in agreement that the patient /surrogate decision maker has been given adequate information and fully understood and agrees to the decision taken by the treating doctor.
- The patient shall sign the consent form. Patients under the age of 18 years cannot sign the consent form as per the legal system. A surrogate decision maker may sign the consent on behalf of the patient if:
    - The patient is incapable of making an informed consent.
    - Pregnant women or woman in labor
    - Mentally incapacitated
    - Unconscious
    - Has received sedation within 3 hours
    - The patient is physically incapable of signing the form

- Terminally ill

- In a life-threatening emergency, consent shall be implied; therefore the patient's signature is not required. In such situations with approval of two consultants and/or one administrator can be obtained.
- The informed consent for the surgery & anesthesia shall be valid for thirty (30) days from the date of signature by the patient or his surrogate decision maker. If there is significant change in the patient clinical condition which has impacted on risk, benefits, alternative and proposed treatment during said period fresh consent shall be obtained.
- The decision regarding the patient's ability to make an informed consent shall be the ultimate responsibility of the Senior Consultant / Consultant.

In the event where the significant other cannot be physically present, the Senior Consultant / Consultant shall discuss the procedure with the family member over the phone, in the presence of another doctor. On obtaining a verbal consent, the Senior Consultant / Consultant shall hand over the phone to the other doctor who shall witness the verbal consent. Both shall sign on the consent form. A patient or the surrogate decision maker may revoke the consent for the procedure at any time before it is carried out. In such an event, the Senior Consultant / Consultant or his designee shall discuss the procedure again and if

the patient or the decision maker still wishes to revoke the consent, then the procedure shall not be carried out. The patient or decision maker shall sign a note to the effect on the signed consent form. The Senior Consultant / Consultant or his designee shall document this in the medical records

B. **Documentation**

1. If preoperative medication (sedation or pain medication) is to be administered, informed consent or verification of informed consent must be obtained **prior** to the administration of such medication.
2. The physician must document in the medical record, on an approved hospital form when available, consent for all therapeutic and diagnostic procedures where disclosure of significant medical information, including significant and frequently occurring risks involved, would assist a patient in making an informed decision whether to undergo the proposed treatment or procedure. Such procedures include surgical and other invasive procedures, other treatments with significant risks, and transfusion of blood and/or blood products.
3. The approved hospital forms must always be completed on all cases involving a procedure for which documented consent is required.

C. **Exceptions:**

Certain recognized exceptions to informed consent include:

1. **Medical Emergency**. A procedure which may otherwise require informed consent may be performed without obtaining prior informed consent in an emergency when the patient is incapacitated and cannot make an informed decision, AND the patient has a life or health-threatening situation requiring immediate treatment such that any delay in treatment would likely result in death, deterioration, or serious permanent impairment.
2. **Patient's Lack of Capacity to Consent.** Patient is incapable or lacks the capacity to give consent. In these cases, suitable alternative procedures, including use of legal guardian/Hair where appropriate, should be initiated if no emergency exists.
3. **Minor**. If the patient is under eighteen years of age, consent should be obtained and documented in the otherwise usual manner from the minor's parent or the minor's legal guardian. The specific facts and reasons the exception applies must be thoroughly documented in the medical record. These exceptions should not be made in lieu of appropriate consent process except under extraordinary circumstances.

D. **Duration of Informed Consent**

1. Informed consent may be considered to have continuing force and effect until the patient revokes the consent, or until circumstances change so as to materially affect the nature of, or the risks or benefits of, the procedure and/or the alternatives to the procedure to which the patient consented. For example, if a patient has been admitted for a specific treatment or procedure, the consent should be valid through the course of the admission unless the patient's condition or treatment changes significantly. In that event, the physician should obtain a new informed consent. Generally, informed consent should be obtained and documented no longer than 60 days prior to a procedure, surgery, or treatment. After this time period, the informed consent should be re-obtained and re-documented by the physician.
2. Revocation - A patient may revoke consent verbally or in writing. This should be communicated to the patient's physician and documented in the medical record.

E. **Informed Consent for Continuing Therapy**

Informed consent shall generally be obtained before each new 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 (not to exceed one year), if:

1. The entire course of treatment is disclosed, consented to, and documented in accordance with this policy, and
2. No material change occurs in:
    a. the risks, benefits of and alternatives to the treatment;
    b. the mode of treatment;
    c. the patient's medical condition; or
    d. the patient's capacity to consent; and
3. Patient does not revoke consent; and
4. Consent is re-obtained and re-documented at least annually. Examples of therapeutic programs covered by this exception include, but are not limited to the following: chemotherapy, repetitive blood or blood products transfusions; peritoneal dialysis, hemodialysis and plasmapheresis procedures.

F. **Role of Registered Nursing Staff/ Residents in the Informed Consent Process**

1. The treating physician has the duty to disclose all information relevant to the patient's decision and to obtain the patient's informed consent. The registered nurse/ resident should verify with the patient and/or by specific

documentation of informed consent in the medical record that consent has been obtained by the physician prior to the procedure or treatment.

2. In the event the nurse/ resident determines that informed consent has not been obtained or documented, the nurse will contact the physician who will complete the consent process, speak with the patient, and/or provide specific documentation of the informed process which has previously taken place.

Informed consent from the patient / family is required whenever patient is undergoing any of the following procedures

1. Transfusion of blood or any other blood product
2. Ascites tapping / Abdominal paracentesis
3. Thoracentesis
4. OCD / Direct Laryngoscopy / Bronchoscopy / Cystoscopy / Colonoscopy / Sigmoidoscopy
5. Bone marrow biopsy / aspiration
6. Fine needle aspiration cytological studies (FNAC)
7. CT guided or US guided FNAC
8. CT scan with contrast & MRI
9. Lumbar puncture
10. Any surgical procedure
11. Foley's catheterization
12. Nasogastric tube insertion
13. Intubation
14. Consent for physiotherapy
15. Consent for dialysis

16. Consent for TMT
17. Consent for HIV screening
18. Consent for Medical Termination of Pregnancy (MTP)
19. Consent Form F (Pre natal diagnostic procedures)
20. Immunotherapy, intravenous or sub-cutaneous
21. Abdominal, pleural or pericardial drainage and drainage tube insertion
22. Central line placement
23. For restraining the patient
24. Organ Amputation
25. Cosmetic Surgical Procedure

9.0 RECORDS AND FORMATS:

Various Informed consent forms related to the care process

Annexure:

Process	When	Validity	Responsibility
General consent	On registration	1 year	Admission / Registration desk personnel
Admission Consent	on admission	Current Admission	Admission / Registration desk personnel
Surgery	Before surgery	30 days if there is no any change in condition	Surgeon performing/ team member
Anesthesia	Before surgery	30 days if there is	Anesthetist

	(during PAC)	no any change in condition	administering / team member
Procedures	Before procedure	Current procedure	Physician Performing
Blood transfusion	Before transfusion	Each Sitting	Physician at ward/ ICU
Dialysis	Before first dialysis	30 days	Dialysis physician
Restraint	Before initiating	24 hours	Physician
Plain CT/MRI & TMT	Before investigation	Current Investigation	Technician/Doctor
Contrast CT/MRI Consent	Before procedure	Current procedure	Physician Performing
HIV Consent	Before screening/ doing HIV test	Current Investigation	Doctor
Physiotherapy	Before doing a procedure	30 days	Physiotherapist
Declaration of pregnant women	Before doing the investigation	Each Test (Radiology)	Technician/ Doctor

Medical Termination of Pregnancy	Before doing procedure	Current procedure	Surgeons Performing
Form F Consent(for pre-natal diagnostic procedures)	Before doing the investigation	Current investigation	Technician/ Doctor
High Risk Transportation	Before shifting a patient	For that care process	Doctor physician