CONSENT

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INTRODUCTION

The granting of permission by the patient for another person to perform an act e.g. permission for a surgical or therapeutic procedure or experiment to be performed by a physician, nurse, dentist or other health care professional is consent.

This is a voluntary agreement made by a well advised and mentally competent patient to be treated or randomized into a research study. The health care provider should provide full disclosure of information.

- Is CONSENT necessary for examination or any procedure including SURGERY???
- The consent is an absolute prerequisite. Other than medical purpose, none can even touch anyone without his permission as per the human rights are concerned.
- CONSENT is an essential medico legal requirement often ignored by doctors.
- Section 13 of the Indian Contract Act lay down that two or more persons are said to consent when they agree upon in same thing in some sense.
- One of the most basic of human rights is freedom from physical interference.
- Consent of examination & treatment is an absolute prerequisite before a doctor approaching the patient.

The CONSENT can be of the following types:

1. Implied Consent: Which is not written as happens in OPD.
2. Express Consent: Anything other than the implied consent described above is express consent. This may be oral or written.
   - ORAL Consent is for minor examinations or therapeutic procedures (injections).
   - WRITTEN Consent is obtained for all the major diagnostic procedures; general anaesthesia or surgical procedures or operations.
   - Written consent should refer to one specific procedure. Blanket permission is of no legal validity.
   - Avoid witness signature by own staff.
   - Prefer witness by two attendant persons with full address and their identity name if it is a thumb impression or signature in a language which is not commonly used.

3. Informed Consent: is in writing & distinct. It contains (in a format) the following:
   1. Diagnosis
   2. Nature of treatment
   3. Risks involved/Prospects of success
   4. Prognosis
   5. Alternative method of every risk

Chaperones: married or elderly woman in charge of a girl. Examination of female patient by male doctor should be made in the presence of a nurse or receptionist or a female relative.

From Whom Consent is obtained:

1. Conscious, mentally sound adults normally give consent themselves.
2. Adolescent between age above 12 years but below 18 years can give consent for medical examination but not informed consent about procedure/operation.
3. If less than 10 years informed consent from parents.
4. If the patient is not conscious or mentally sound, guardian next to kin can give consent on behalf of the patient.
5. In any procedure affecting the rights of spouse, e.g. sterilization, hysterectomy, artificial insemination informed consent from spouse is necessary.
6. The consent given may be invalid if the act consented is unlawful i.e. criminal abortion.

Situations where Consent need not be obtained:

- If the patient is unconscious & not accompanied by anyone & needs urgent medical treatment. No consent is required and the doctor can take decisions himself (good faith).
- U/S 53 (1) of Cr. P. C.. An accused can be examined at the
request of the police even by force.
• A court may order examination or treatment.
• In medical emergencies like fasting unto death.

How to Take Informed Consent:
• It should be in proper format.
• Blanket consent is legally incorrect and invalid.
• It should be filled in and duly signed before any operation/procedure.
• It must include O.P.D. / indoor registration no., name, age, sex and complete address.
• Signature or thumb impression should be attested giving the details of name/address/relation with patient etc. specially when it is in different language like Urdu, because most of the doctors are not knowing the written language.

INFORMED CONSENT FORMAT
Authorization for Medical Treatment, administration of Anaesthesia and performance of surgical operation and/or Diagnostic/Therapeutic Procedure.

1. I hereby authorize the Hospital and those the Hospital may designate as staff to perform upon the following medical treatment. Surgical operation and/or diagnostic/therapeutic procedures.
2. It has been explained to me that, during the course of the operation/procedure, unforeseen conditions may be revealed or encountered which necessitate surgical or other emergency procedures in addition to or different from those contemplated at the time of initial diagnosis. I therefore, further authorize the above designated staff to perform such additional surgical or other procedures as they deem necessary or desirable.
3. I consent to the administration of anaesthesia and to use such anaesthetics as may be deemed necessary or desirable, except to the following exceptions : (Indicate exception or none)
4. I state that I am not suffering from Hypertension/ Diabetes/ Bleeding disorders/heart diseases or ---------
5. I also state that I am not suffering from any known allergies or drug reactions.
6. I further consent to the administration of such drugs, infusions, plasma or blood transfusions or any other treatment or procedures deemed necessary.
7. The nature and purpose of the operation and/or procedures, the necessity thereof, the possible alternative, methods, treatment, prognosis, the risks involved and the possibility of complications in the investigative procedures/investigations and treatment of my conditions/diagnosis have been fully explained to me and I understand the same.
8. I have been given an opportunity to ask all/any question and have also been given option to ask for any second opinion.
9. I acknowledge that no guarantee and promises has been made to me concerning the result of any procedure treatment.
10. I consent to the photographing or televising of the operations or procedures to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures or by descriptive texts accompanying them.
11. For the purpose of advancing medical education, I hereby give consent to the admittance of observers to the operating room.
12. Also give consent to the disposal by hospital authorities of any tissues or parts which may be removed during the course of operative procedure/treatment.

I CERTIFY THAT THE STATEMENTS MADE IN THE ABOVE CONSENT LETTER HAVE BEEN READ OVER AND EXPLAINED TO ME IN MY MOTHER TONGUE AND I HAVE FULLY UNDERSTOOD THE IMPLICATIONS OF THE ABOVE CONSENT AND FURTHER SUBMIT THAT STATEMENTS THEREIN REFERRED TO WERE FILLED IN AND ANY INAPPLICABLE PARAGRAPHS STRICKEN OFF BEFORE I SIGNED/PUT MY THUMB IMPRESSION.

BLANKET CONSENT
Blanket consent is a vague or non-specific consent which is legally incorrect. The following example is blanket consent.

“I am agree and consent to be operated for my stomach trouble or “I consent for operation on my abdomen for the cause of pain abdomen.”(Signed the patient).

All consent must be specific and clear for specific procedure or operation. If the right kidney is to be operated the consent must be specified for right kidney only. If on opening of abdomen the surgeon feels to operate on appendix, he is to take separate consent simultaneously.