SOP | PATIENTS CONSENT
Global Edition

Institute of Medicine & Law
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Global SOP on Patients Consent 2022

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1. Consent in Non-Emergency Situations - General Procedures

1.1 Take consent only of the patient in a non-emergency situation if the patient is adult (also refer to Clause 6.1), capable (also refer to Clause 6.5), and oriented (in time, place, and person). Establish and confirm mental capacity of all adult patients irrespective of the age. Do not consider older patients incapable by default. In appropriate cases, especially high-risk cases (also refer to Clause 1.16), a confirmation from the next of kin, preferably a first-degree relative (not mandatory), may be taken or they may be asked to sign as a witness (also refer to Clause 1.17) (Advisable). In case next of kin is not available at that point in time, any relative, or even an unrelated friend / neighbour / attendant may be asked to sign as witness.

1.2 Take 'proxy' consent from capable adults responsible for incapable patients. (also refer to – 'Chapter 6. Minors / Incapable / Emergency patients – Proxy Consent)'. Any person authorized by the patient through living wills / Advance Medical Directives (AMD) (includes instructions such as Do Not Intubate {DNI}, Do Not Resuscitate {DNR}, Do Not Attempt Resuscitation {DNAR}, Do Not Attempt Cardio Pulmonary Resuscitation {DNACPR}, AND {Allow Natural Death}) / lasting power of attorney for health / or such other documents can also give proxy consent for that patient. In appropriate cases, signature of witness/es (also refer to Clause 1.17) may also be taken (Advisable).

1.3 Do not take consent of spouse, children, or parents (instead of the patient) in case of an adult, capable and oriented patient. However, they may be asked to sign as witnesses (also refer to Clause 1.17), especially in high risk cases, medical emergencies, very old patients, patients with cognitive defects and so on (Advisable).

1.4 Take patient's written consent rather than not taking one.

1.5 Take written consent only for those investigations / diagnostics and therapeutic procedures, major or minor, IPD or OPD, that require invasive intervention. Take written consent (advisable, not mandatory) for certain non-invasive therapeutic measures such as diathermy, lithotripsy, nuclear-scan, CT scan using dye, MRI, EEG, PET, BiPAP, chemotherapy, hormone replacement therapy, drugs having serious side-effects, high risk medication, high dose steroids, immunosuppressants, and such other high-risk cases (this list is not exhaustive but only indicative) (also refer to Clause 1.16).

1.6 No written consent is required for:

I. For routine investigations such as drawing of blood.

II. From OPD patients on routine visits unless an invasive procedure has to be performed in the OPD.

III. For non-invasive diagnostic / therapeutic procedures such as ECG, plain CT scan, and so on.

1.7 Do not reduce consent to a mechanical / routine act. Do not influence the patient in any way. Do not make value judgments about the patient's preferences. Consent is a process and not merely an act of signing the consent form. It involves providing relevant information about the proposed treatment / intervention (also refer to Clause 1.13), discussing with the patient, ensuring that the patient has understood the information, arriving at a mutual agreement, and then filling and signing the consent. Provide information that is relevant to that particular patient, his/her general health status, social and financial situation, and which will help the patient to make an informed and independent choice.

1.8 Do not deviate from what has been consented and agreed, except in life-threatening conditions, for bonafide reasons, and only in the patient's interest (also refer to Chapter 8: Additional / Alternative / Extension during a planned surgery / procedure).

1.9 Take consent only after appropriate disclosures and proper explanation, neither by unduly scaring nor falsely alluring the patient into acceptance. Follow guidelines on counselling, if any, issued / framed by revered / recognized / national medical associations or professional bodies for that particular therapy / intervention.

1.10 Explain and counsel in the language / dialect that can be understood by the patient. In case services of a professionally qualified translator / interpreter have been taken, especially in case of international patients, the translator / interpreter must write his/her name, also sign the consent as witness and record specifically that he/she has explained in the language understood by the patient and only thereafter the patient has signed the consent. Take proof of identity proof of the translator / interpreter and also ensure that he/she is legally capable and not below 18 years of age.

1.11 Explain and counsel in simple non-medical terms. Provide information in lay terms. Brochures / informative booklets about the interventions / therapies could be provided to the patient (Advisable) (also refer to Clause 1.19).

1.12 Explain and counsel the various aspects of the proposed treatment / intervention to the patient by handwritten notes / diagrams / figures / images / models / posters of organs / systems / diseases in appropriate cases and only if the same are easily available. Try to give pictorial information in case of children and illiterate patients. Append these with the consent form. Thereafter follow the protocol, as far as applicable, prescribed in Clause 3.12 (Advisable).

1.13 Give sufficient information, disclose to the patient and duly record in the consent:

I. Medically approved name of the treatment / surgery / procedure.

II. Nature, purpose (intended benefits), consequence and outcome of the treatment / surgery / procedure and the trouble / disease / complication for which the same is advised.

III. Likely prognosis in accordance with the accepted medical practice.

IV. Risks involved - the most commonly occurring risks and not the rare ones (also refer to – 'Chapter 4. Risk information)'.

V. Commonly occurring life-threatening and non-life-threatening complications / consequences / discomfort / disadvantages - Even complications / consequences that are rare but likely to affect vision, hearing, motor, and brain functions, or may result in amputation, disability, paralysis, or serious bleeding (Advisable). VI. Special care and its level, if any, that may be required post treatment / surgery / procedure. VII. Available appropriate alternatives (includes the option of refusing) – The relative advantages and disadvantages of each of the available alternatives and the preferred one with reason/s. VIII. Consequences of refusal, especially adverse, regardless of the patient's refusal or acceptance. IX. The fact that the surgeon may come across unexpected situations during the course of surgery and it may require additional / alternative / extension other than what has been consented, and that the patient consents for the same.

1.14 Give the patient reasonably enough time, depending on the situation, to take the decision for giving consent after counselling except in emergency situations such as caesarean, evacuating clot setting on brain, need for mechanical ventilation, and so on. If the clinical condition of the patient changes during this period of patients' contemplation, initiate the process for taking fresh consent.

1.15 Multi-stage treatment:

I. Take single and comprehensive consent explaining the different stages one after the other even if the different stages are contemplated to be performed on different dates.

II. Enumerate each stage specifically and separately in the consent.

III. Inform the patient that he/she may withdraw consent at any stage of treatment. Record this aspect specifically in the consent.

IV. After taking such consent, if the patient's condition changes significantly and/or any deviation is contemplated in the subsequent stages from the consented course, a fresh consent must be taken.

1.16 High-risk Consent:

Inform the patient specifically, duly record the same in the medical records, and take an elaborate high-risk consent if:

I. Unusual requests are made by patient / attendants, abnormal / suspicious circumstances, and such other conditions.

II. The treatment / recovery is expected to take a very long time.

III. The rate of failure is high.

IV. The technique / procedure / drug / protocol is relatively new / critical / complicated.

V. Relapse is common.

VI. Presence of any co-morbid condition that may interfere with the surgery / procedure / treatment.

VII. The patient is in a critical state or is even otherwise at high risk.

VIII. Removal of any organ / limb is a possibility.

IX. You are proceeding with a surgery / procedure / treatment in spite of abnormal parameters.

X. The commonly occurring complications of the proposed technique / intervention / drug / protocol are serious / life-threatening.

1.17 Independent witness:

I. Take patient's consent in the presence of minimum one independent witness in case of high-risk consent (also refer to – Clause 1.16).

II. The witness must be legally capable - adult, conscious, and oriented.

III. Ideally the witness should not be connected / employed / related to the doctor, hospital, or patient.

IV. The witness must write in his / her handwriting on the consent form that the patient has informed the witness that the patient was explained the content of the consent form in the language / dialect known and spoken by the patient; the patient has consented to the same; and thereafter the patient has put his / her signature / thumb impression on the consent form in front of the witness.

V. The witness must then sign the consent form, write his / her name, relation with the patient, and contact coordinates in BOLD letters.

VI. A copy of identity proof of the witness must be taken for the purpose of traceability and preserved with the consent form.

VII. Translator / interpreter whose services have been used could be an independent witness for that particular patient (also refer to Clause 1.10).

1.18 Record specifically in the consent form if a consultant / surgeon has agreed to manage the patient only for a specific period, only to perform the surgery / procedure or is taking a planned leave during the immediate post-surgery period and that thereafter the patient will be managed by other / another designated / assistant doctor.

1.19 Prepare and provide the patient with a brochure / informative booklet, preferably in the local language/s, describing the therapy, risks, prognosis, and advantages of the treatment / interventions especially in case of rare / new / complicated / risky - treatments / surgeries / procedures. The aforesaid should be provided beforehand and the patient must be given a reasonable time to contemplate to take a decision. Append a copy of such brochure / booklet bearing patient / attendants acknowledgment of receipt with the consent form.

1.20 Check specifically whether the patient's signature on the consent form is in the official language or not. If the signature is not in the official language follow the protocol, as far as applicable, prescribed in Clause 1.21.

1.21 Taking consent of a patient not conversant with the official language / illiterate / semiliterate:

I. Exercise greater caution.

II. Give the requisite information in the language / dialect known to the patient.

III. If the doctor cannot speak the language / dialect known to the patient involving a professionally qualified translator / interpreter is the best option (also refer to Clause 1.10). In the alternative, the patient must be asked to bring someone who can understand, translate, and explain to the patient. If the patient expresses inability to bring anyone, a staff member, or someone known to the doctor can be involved, but only as a last resort. Record this fact in the consent specifically (Advisable).

IV. Take thumb impression or signature of the patient.

V. Take signature of an independent witness (also refer to Clause 1.17) (Advisable).

VI. Specifically record the fact that consent was taken after counselling in the patient's language.

VII. Ensure that the patient does not write anything on the consent that cannot be understood by the doctor / hospital staff.

1.22 Take thumb impression on the consent of a 'literate' patient who is unable to sign due to any reason. Record specifically the reason for taking thumb impression and also take suitable endorsement from the patients' relatives / friends / attendants on the consent, if possible. Follow the protocol, as far as applicable, prescribed in Clause 1.21.

1.23 Therapeutic Privilege:

A doctor withholding information from the patient for therapeutic purpose:

I. Exercise this option very rarely, in the patient's interest and only if disclosure would otherwise interfere with treatment, adversely affect the condition / recovery of the patient, or in case of certain diseases that are considered taboo.

II. Explain the reasons for withholding any information from the patient to the patients' attendants / relatives and take their written endorsement of having received this information.

III. Take opinion of other doctors involved with the patient and if they agree with your decision of withholding information from the patient take their written endorsement (Advisable).

IV. Any request to withhold information made by patient's attendants / relatives, especially spouses, children or parents must be given due importance, but the final decision must always be taken by the doctor. Take their request in writing, take their proof of identity, and duly preserve both with the consent.

1.24 Procedures / treatment with pure cosmetic values (generally performed by dermatologists, cosmetologists, dentists, plastic surgeons, and so on) where usually the acceptance of post-procedure / treatment results is highly subjective, perceptive, and sensitive - Take additional consent of the patients' spouse / parents / relatives / friends but only after taking specific consent of the patient for the same (Advisable).

1.25 No separate consent is required for procedures which are part of the surgery for which the patient has consented. Ensure that this additional part of the surgery has been specifically explained to the patient and also recorded in the consent.

2. Consent Form

2.1 Printed consent form in the official language can also have its printed translated version in the local language appended as a separate leaflet or printed on the reverse side. (Advisable)

2.2 Printed consent forms must have enough blank spaces for filling complete and additional information. If any part of the information is documented in any other space other than the designated space or on a separate sheet, follow the protocol prescribed in Clause 3.12.

2.3 Consent forms can have suitable columns / spaces for the patient to indicate whether the patient has executed any AMD / Living Will / lasting power of attorney for health / or such other documents. A copy of AMD / Living Will / lasting power of attorney for health / or such other documents should be appended

with the consent form. AMD / Living Will / lasting power of attorney for health means and includes instructions given by a person regarding withdrawing / refusing treatment in certain conditions.

3. Filling the Consent Form

3.1 Consent form printed in the local language, or the language understood by the patient must be filled in the same language (Advisable)

3.2 Consent form can be filled / written by a doctor / nurse / counsellor. (This clause is for filling of the consent form and should not be confused with signing of the same).

3.3 Fill the consent form in one sitting even though counselling the patient may take more than one sitting. (Advisable)

3.4 Avoid changing the pen or the person who is filling the consent form midway. Maintain uniformity in filling the consent form. (Advisable) (This clause is not applicable for digital consent forms.)

3.5 Make entries in the designated spaces only. Mention specifically that extra pages have been annexed if the designated space is inadequate. Number the pages if consent is of more than one page.

3.6 Fill the consent form completely. Do not leave any space blank in a printed consent form. Write 'Not Applicable' or 'NA' in spaces where nothing has to be written. (Advisable)

3.7 Try to avoid alteration, addition, overwriting, or erasure while filling the consent form. In case any change has to be made, encircle the wrong portion, cancel with a single stroke and write the correct entry besides it with counter signatures, rather than erasing or putting white ink. Filling a fresh consent form would be a better option. (Advisable) (This clause is not applicable for digital consent forms.)

3.8 Take the patient's signature / initials on every page of the consent form. (Advisable)

3.9 Doctor-in-charge of the patient / principal surgeon / principal anaesthetist must also sign their respective consent forms.

3.10 Avoid using abbreviations / acronyms.

3.11 Writing a new sentence on a printed consent form below the space designated for the patient's signature

- Take patient's signature with date and time below this newly added sentence.

3.12 Additional page/document appended with a consent form:

I. Append all these papers after the printed consent form.

II. Number them serially. The printed consent form must also be numbered.

III. Take patient's signature on each page.

IV. Preserve these additional papers with the consent form for the requisite period.

4. Risk Information

4.1 Explain and record the most commonly, early as well as late occurring risks in the consent.

4.2 All material risks, especially those having higher probability of occurrence, must be specifically spelt out to the patient and duly enlisted in the consent. The exact percentage of the risk as stated / accepted by medical science need not be specifically mentioned in the consent.

4.3 Answer questions raised by patients about a specific risk and record the same in the consent.

4.4 During pre-surgery / procedure / treatment counselling, disclose to the patient and duly record in the consent:

I. If the failure rate is higher, or relapse or recurrence is a known possibility.

II. Risk involving loss / diminution of life, vision, hearing, mental function, function of limbs and organs or may result in amputation, paralysis, or serious bleeding even though the risk may be rare. (Advisable)

4.5 Avoid disclosing risks that are remote, or will frighten, or confuse the patient (Advisable). Find ways for discussing risks without confusing or frightening the patient.

5. Emergencies

5.1 Do not wait for consent in emergencies if waiting could be detrimental to the patient. Take appropriate decisions in the best interest of the patient.

5.2 Take consent from the patient even in emergencies, if the patient is adult, capable and oriented.

Only when an emergency patient is unconscious / incapable to give consent:

I. Proceed with lifesaving treatment / surgery by taking oral consent of the patient and in appropriate cases even without consent.

II. Take proxy consent if the relatives / attendants are present at that point in time, or even from another doctor / Medical Superintendent / Head of the hospital / Public Relation Officer / Social worker, only if possible, and without much effort.

III. Duly inform the hospital authorities.

IV. Record specifically in the patients' medical records and / or the consent form the life-threatening emergency as well as the reason/s for not obtaining consent, or for obtaining proxy consent. This exercise can even be done once the emergency is over.

6. Minor / Incompetent / Emergency Patient - Proxy Consent

6.1 Consent and Age (The age of majority is considered as 18 years in this Chapter. Substitute the same with the age of majority of your country.)

I. Child patient below 12 years - Take consent of the parents / guardian only.

II. Child patient between 12 to 18 years - Take consent of the patient as well as the parents / guardian.

III. Adult patient above 18 years - Take consent of the patient only.

6.2 Proxy consent 'giver' for minor / incompetent / emergency patient:

I. Spouse / blood relatives / any other relative, preferably a first-degree relative (not mandatory)

II. Biological parents / guardian (both legal as well as de-facto).

III. Even the teacher / warden who brings the child to the doctor / hospital but only in an emergency.

IV. Consent of any one of the parents is valid and binding even if there may be difference between both the parents.

V. Person not connected or related with the patient but who may have brought such a patient (e.g. in accident cases).

VI. Medical Superintendent / Head of the hospital or such other responsible person in institutions / hospitals.

VII. Person/s expressly indicated by the patient to give consent in accordance with his / her Advance Medical Directive (AMD) as prescribed by the Supreme Court.

6.3 Taking proxy consent

I. Counsel / explain in the language understood by the proxy consent giver. Follow all other protocols of taking consent of the patient as far as possible.

II. Verify and record specifically the name, address, telephone number and relationship with the patient of the person from whom proxy consent has been obtained. It is advisable and not mandatory to take a self attested photocopy of the proof of identity (having photo, age and signature) of the person giving proxy consent for the purpose of traceability. Match the signatures on the consent with that on the proof of identity.

III. Record specifically the reason/s for obtaining proxy consent in the consent.

IV. Further directions / consent during the treatment may be sought from such a person.

6.4 Patient's orientation seems doubtful - Follow the protocol for incompetent patients rather than treating the patient as a competent one (Advisable).

6.5 Incapable Patient - Means and includes minors; a person with mental illness who lacks the mental capacity or suffers from cognitive impairment or decline; unconscious or anesthetized with alteration of sensorium; under the influence of drugs, sedatives, alcohol or substances that cloud consciousness or judgment; in such pain and agony that the patient is not in a position to give consent or complete other formalities; and so on. A disoriented patient is an incapable patient.

6.6 A patient in labour with severe pain is competent to give consent. But in appropriate cases proxy consent can also be taken.

7. Surgery / Procedure / Intervention

7.1 Do not take 'blanket' consent, general in nature, at the time of admitting a patient for surgery / procedure.

7.2 Take consent closer to the day of the surgery / procedure. (Advisable)

7.3 Disclose to the patient during pre-surgery counseling and record specifically in the consent if:

I. Any decision may have to be taken on the operation table after opening the patient - Even if it is the choice of not proceeding further after opening such as in the cases of advanced cancer or tuberculosis.

II. Damage / removal of important organs is a possibility.

III. Any other alternative/s may have to be adopted after opening the patient. Record specifically all such alternatives.

IV. The surgery / procedure may require multiple stages / sessions / sittings

V. Corrective surgery / procedure may be required to deal with known post-surgery complication/s.

VI. Re-operation / second intervention may be needed.

VII. Relapse / recurrence / failure is a known possibility for that particular surgery / procedure / disease.

7.4 Record the date fixed for performing a scheduled, non-emergency elective surgery / procedure in the consent.

7.5 No fresh consent is required if the surgery / procedure is rescheduled but without any change to whatever was originally consented by the patient. However, if the surgery is postponed by more than 48 hours, contemplate of taking a fresh consent or just add a line below the already signed consent validating it on the current date by signing afresh (Advisable).

7.6 Take composite consent for both the surgery / procedure and re-exploration, if foreseeable and anticipated. Take fresh consent for non-emergency re-exploration / repeat intervention to correct complications suffered by the patient during / after the course of treatment / intervention.

7.7 Take separate consent for each procedure / surgery if two or more surgeries / procedures are to be performed together either by the same surgeon or by different ones.

7.8 Take separate and specific consent for each and every foreseeable and anticipated alternative surgery / procedure. Consent for a difficult / complicated surgery / procedure does not automatically operate as consent for a comparatively easier / simpler alternative. Additional / alternative / extension that may have to be performed during the course of a surgery / procedure is not intended to be covered by this clause (also refer to – Clause 8.3).

7.9 Take 'high-risk consent' (also refer to - Clause 1.17) in appropriate cases. Inform the patient / attendants accordingly and record the said fact specifically in the medical records also.

7.10 Anaesthesia:

I. Take separate specific consent for anesthesia.

II. Duly record the type of anesthesia - general / local / epidural / spinal / nerve block or any other in consent.

III. Take advance consent for each option if multiple anesthesia options are contemplated in alternative.

IV. Follow other protocols / procedures of general consent as far as possible which are applicable / relevant to anesthesia.

7.11 Record specifically name of the principal surgeon and the principal anaesthetist in both, the consent for surgery as well as the consent for anaesthesia.

7.12 Take a fresh consent if the doctor scheduled to perform a surgery / procedure for whom the patient had specifically consented is changed.

7.13 Non-availability of the surgeon for post-surgery care especially when the surgeon has agreed only to perform the surgery / procedure and thereafter the day-to-day management would be the responsibility of others or of another designated doctor or a team of doctors:

I. Inform the patient in advance of the aforesaid, and record it specifically in the consent. Emergencies are exceptions as far as informing the patient is concerned.

II. Provide proper substitute even in an emergency not anticipated by the surgeon.

7.14 Confirm before starting every surgery / procedure whether the OT nurse has personally checked the consent form/s in the patient's medical records, it is signed by the patient and complete in all respect

7.15 In case of an accidental injury / mishap / complication during a surgery / procedure follow the protocol, as far as applicable, prescribed in Chapter 8. - 'Additional / Alternative / Extension during a planned surgery / procedure'.

7.16 Do not take separate consent for sending any part / tissue / fluid / organ removed from the patient's body for usual cytological or histopathological examination.

7.17 Take separate and specific consent for sending any part / tissue / fluid / organ removed from the patient's body for research purposes.

8. Additional / Alternative / Extension During a Planned Surgery / Procedure (same anesthesia period)

8.1 Discuss, explain and take specific consent beforehand for any additional / alternative / extension that may have to be performed during a planned surgery / procedure when the patient would be unable to take an informed decision.

8.2 Record specifically the name/s of each of the anticipated and foreseeable additional / alternative / extension in the consent.

8.3 Additional / alternative / extension during the course of a surgery / procedure without thepatient's specific consent.

I. Do not proceed without specific consent only because it would be beneficial to thepatient, or would save considerable time and expense of the patient, or relieve the patientfrom pain and suffering in future.

II. Proceed only if it is 'necessary in order to save the life, limb or organ, or preserve thehealth of the patient and it would be unreasonable to delay'.

III. Take written consent, if possible, from the patient's attendants (Advisable).

IV. Record specifically and elaborately the reason/s for the additional / alternative /extension in the intra-surgery notes and in the written consent taken from the patient'sattendants(if one has been taken)

9. Blood / Blood Products Transfusion

9.1 Take separate and specific consent for transfusion of blood / blood product/s in all cases where transfusion is foreseeable and anticipated.

9.2 In emergencies and in cases where blood / blood products transfusion could not have been foreseeable and anticipated, blood / blood products transfusion even without consent is permissible except in cases where a valid living will / AMD / lasting power of attorney for health / or such other documents prohibiting blood transfusion is in force and the same is in the knowledge of the surgeon / anaesthetist.

9.3 Take consent for blood / blood products transfusion for all surgeries / procedures along with consent for surgery / procedure. (Advisable)

9.4 Counsel the patient that even though transfused blood / blood product/s is tested for HIV, HCV, Hep B and other microbial contamination / transmission according to the current guidelines, yet there remains a minimal but potential probability of these diseases getting transmitted to the recipient as they cannot be always detected by tests done in blood banks (Advisable).

9.5 Consent for multiple transfusion of blood / blood product/s once given by the patient remains valid for multiple transfusions in the same sitting or multiple sittings spread over a few days. Record this specifically in the consent form.

9.6 Patients who are transfusion dependant (haemophilia, thalassemia, etc.) or require to undergo procedure for a long time (dialysis) - Consent for transfusion of blood / blood product/s once given by the patient to a doctor / hospital remains valid till the time it is specifically withdrawn by the patient. Record this specifically in the consent form.

10. Delay / Refusal to Consent

10.1 Record specifically in both the consent and the medical records, if there is any delay / failure / hesitation / unwillingness / refusal / dissent on the part of the patient to give consent and the reason/s for the same if known. Also explain / record implications of delay / refusal

10.2 Follow the protocol, as far as applicable, prescribed in Chapter 12. - Patient giving part consent and part refusal.

10.3 Record specifically the date and time when the patient's consent was sought and when the patient gave or refused to give consent in both the medical records and consent.

11. Patient Giving Part Consent or Part Refusal

11.1 Contemplate whether the consented part can be disconnected from what has been refused.

11.2 Weigh the consequences of part consent - In appropriate cases and non-emergency situations, the doctor has a right to refuse to provide a suboptimal treatment if the harm is likely to outweigh the benefits.

11.3 In case one proceeds with part consent - clearly record that the patient has given only part consent in the consent form; get the consent form attested by minimum one independent witness (also refer to Clause 1.19); and also record this fact in the patient's medical records.

12. Patients Refusal of the First / Best Option and Choice of Another Medically Acceptable Option

12.1 Take elaborate consent recording both the best option and the other option chosen by the patient that is also medically acceptable.

12.2 Explain to the patient and specifically record the relative advantages and disadvantages of both the options.

13. General Provisions

13.1 Consent must be voluntary and informed and can be implicit or explicit. It is a fundamental acknowledgement of patients' autonomy and freedom of choice. Consent given and taken appropriately enhances and strengthens the doctor-patient trust.

13.2 In jurisdictions where statutory / regulatory provisions regarding consent are in force and the same are contrary to or inconsistent with provisions of this SOP, the former will have precedence and must be followed.

13.3 The term official language has been used in this SOP to denote the official language of that country, State or part. In appropriate cases, it would mean and include the local language also.

13.4 The clauses relating to printed consent forms in this SOP should be suitably adapted In jurisdictions where digital consent forms are used.