FOGSI's UNIFORM CONSENTS

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FROM THE DESK OF PRESIDENT

Dr. Alpesh Gandhi

Dear FOGSIANS,

I wish season's greetings to you!

It is an honour for me to present to you this very useful booklet on FOGSI's Uniform Consents.

With medico-legal awareness on the rise, most hospitals across the country do obtain consents from their patients before a procedure or surgery. However, the definition of informed consent is still somewhat vague. Since each institution has its own type of consent, the amount of information included, the number of people signing it, the timing of the consent, whether witnesses were present etc, differs greatly. We therefore had a plan to develop guidelines for a uniform consent pattern for most common procedures, which would simplify consent taking and expedite the process in case of emergencies. Also, with a standard format, these consents will be more easily accepted in a legal setting and reduce unnecessary legal hassles.

Our theme for the year has been Safety first: for Indian women and FOGSIANS. 70% of ML cases are because of improper consents and counselling or not taking a consent. Medicolegal safety, and the ability to be able to practise without fear of persecution forms a major aspect of that safety.

We developed more than 30 such uniform consents for common ob-gyn procedures, surgeries, interventions. We prepared as per the advice and the landmark judgements of the Hon. Supreme court of India. We also wish to bring it in both the languages - English and Hindi.

At the beginning of my term as President FOGSI, this project was one that we had promised and prioritized and I am happy to say we have delivered in the stipulated time. This could not have been achieved without the hard work of all the people involved. I would especially like to thank Dr. Sanjay Gupte, pioneer in Medicolegal field in FOGSI for writing the foreword for this prestigious book. A special thanks to our national Medicolegal experts Dr. M.C. Patel, Dr. Dilip Walke, and Dr. Nikhil Datar for painstakingly drafting and compiling this entire volume. I thank the Prof. Anand Raut, Prof. Dr Nikhil Datar from Maharashtra National Law University for their technical and legal support and inputs, which had enabled us to construct such technically sound consents. I am thankful to FOGSI office bearers for supporting the very useful project.

We have also consulted with seven national experts from different fields outside FOGSI. This team of legal professionals have guided and advised us to create airtight, legally sound documents that may hold up in any court. We are very grateful for their wholehearted involvement and expert opinions.

Our team has worked hard on constructing these documents and I expect these will be put into day to day use as soon as possible.

I wish you all a very safe Obst-Gynaecology practice with good outcome.

Warm regards

Yours sincerely

Dr Alpesh Gandhi

President, FOGSI- 2020-21

FROM THE DESK OF CHAIR - ETHICS COMMITTEE - FIGO

Dr. Sanjay Gupte

I am very happy to write this foreword for the book of uniform consents that is created by The Federation of Obstetric and Gynaecological Societies of India, for its members. At the outset let me congratulate Dr. Alpesh Gandhi, the President of FOGSI for initiating this onerous work and allotting it to the three experts in the field, Dr. M. C. Patel, Prof. Dr. Nikhil Datar and Dr. Dilip Walke. This is one of the steps in fulfilling the agenda that Dr. Alpesh had promised to the FOGSI members through his theme 'Safety first: for Indian women and for FOGSIANS'. I must complement the team for painstakingly working on the individual consents and also involving legal experts from Maharashtra National Law University for their approval.

Consent in clinical practice has always been a contentious issue, especially because it is based on the fiduciary relationship between the doctor and the patient, and also because the right to make decisions about one's own body is inalienable. The consent for medical treatment is extremely important because it promotes patient's autonomy, it protects the patient from fraud and duress, it also encourages self-scrutiny by medical professionals and promotes rational decisions. Over the years, medical consent has been evolving. For many years it used to be just a one line consent allowing the doctor to practically carry out any treatment or procedure, the so called 'Blanket consent'. Now of course, the courts have shifted, and rightly so, to the informed consent with all its essential characteristics. Not only that, the consent has to be valid; which involves voluntariness of the consent, capacity of the consentee after being imparted adequate knowledge of the procedure.

Consent can be of various types, either Expressed consent or Implied consent. For medical procedures, implied consent is only valid at two extremes, one for physical examination and on the other end, when the procedure is considered lifesaving. Sometimes there can be a Surrogate consent given by the guardian, court or rarely a doctor.

In the classical judgment viz. Samira Kohli Vs Dr. Manchanda (January 2008), The Supreme Court of India has dealt with extensively and specifically, the matter of consent and this has now become the case law for our country. The Supreme

Court put down definitive characteristics of the medical consent. It was said that the consent should be real and valid, that means the patient should have the capacity and the competence to consent. His consent should be voluntary and should be on the basis of adequate information regarding the procedure. Furthermore, the Court has also specified what is meant by adequate information. It involves (1) Nature and procedure of the treatment, its purpose, benefits and effects (2) Alternatives, if any available (3) An outline of the substantial risk (4) Adverse consequences of refusing the treatment. I have described all the above in details because, I am happy to say that the expert team creating this book has taken great efforts to follow these Supreme Court guidelines for all the consents in this book. I am making a point of mentioning this because prima facie, after going through this book, a common view point may be that, these consents are extremely lengthy, could be time consuming to explain to the patients and sometimes even impractical when the patient may have very little understanding capacity. But we all will have to make an honest effort to put these in practice if we are to satisfy the legal authorities as well as to engage our patients in the decision making process. I am sure with the experience gained, there will have to be further modifications and newer versions of the some of these consent documents and I am equally sure that the authors are aware and willing for it.

Overall this has been an excellent effort and we must compliment the authors for undertaking and completing such a massive task.

I, on my part, am very happy to be associated with this honorable effort which is ethically significant in improving the relationship between the patients and the physicians and at the same time reducing the risks to both of them.

Dr. Sanjay Gupte
President FOGSI 2010
Chair- Ethics Committee – FIGO
(The International Federation of Gynecology and Obstetrics)

FROM THE DESK OF EXPERTS

Dr. M C Patel

Prof. Dr. Nikhil Datar

Dr. Dilip Walke

At the outset we thank the President FOGSI 20-21 for giving us this opportunity to draft "surgery specific consents" for the benefit of FOGSIANs.

We began with brainstorming about the format of the consents. On one hand we were conscious of legal expectations from Indian Courts and on the other hand we took into consideration the practical challenges faced by doctors while taking consent. The aim was to create such drafts that provide adequate medicolegal protection as well as sufficient information to the patients about the procedure / surgery.

We referred to several case laws on the topic. The "Maharashtra National Law University", a premier national law university guided us during this work.

Thus, these consent forms are vetted medically and legally both. We are confident that proper use of these forms will provide profound medicolegal protection to our members.

We request you to read these consents, use them in clinical practice and give your inputs & suggestions which may be incorporated in the next version. You may write to

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fogsi2007@gmail.com

Thanks

Dr. M C Patel

Prof. Dr. Nikhil Datar

Dr. Dilip Walke

Thank you for your guidance & Expert Opinions . . . .

1. Hon'ble Justice **Kaushal Jayendra Thaker** - Hon'ble Judge, High Court of Judicature at Allahabad

2. Hon'ble Justice **Mr. Ambadas Joshi** - Former Judge of Bombay High Court and presently Lokayukta of Goa.

3. **Adv. Shirish Deshpande** - Learned advocate and President of Mumbai Grahak Manch

4. **Dr. S. M. Kantikar** - Member national Consumer dispute resolution commission

5. **Adv. Dr. Joga Rao** - Anchoring the professional activities of Legalexcel – A Law Firm of Advocates, Solicitors and Healthcare Consultants.

6. **Dr Anant Raut** - HoD (PG), Deputy Director Centre for ICT Law, Assistant Professor, Maharashtra National Law University Mumbai.

HOW TO USE FOGSI'S CONSENT FORMS

- It has been a norm to use a general consent form for all the surgeries. With the changing medicolegal scenario, we have created consent forms specific to the procedure/ surgery.
- The consent form has two parts. Part I provides information about procedure that patient needs to know about. This information is curated according to medical and legal requirements.Part II is "undertaking" that patient's signature has to be obtained.
- Kindly note that we have divided the book into three sections. First section deals with general consents. They are self explanatory documents and information and undertaking , both are incorporated in the same form.
- Section 2 contains "Procedure specific information". The last section deals with "Undertaking". Combination of procedure specific information and signed undertaking together will show case that the patient was genuinely given necessary information and the patient consented for the same. Thus, It is expected that the patient reads both the parts and signs at appropriate places on the forms.
- Part I (information) should be handed over to the patient when counselling is done. Patient should write her name and sign at the end of the paper when she receives it. She MUST be told to bring the paper back when she comes for admission for the surgery/ finalising the surgery.
- Part II (Undertaking) should be signed by the patient before undergoing the surgery. For elective surgery, part II will be signed on orafter admission. Part I should be kept along with Part II.
- It may be a good practice to request the patient to write a sentence in herown hand writing and in her own language at the end of the form. This sentence may be "I have read/ I have been explained the above- mentioned information and I have understood the same.".
- Please note that there are few blank spaces kept in the form.These need to be filled up completely. Some of these may be used to capture individual risks or issues. For example, if you are taking consent for laparoscopic hysterectomy for a patient who has low ejection fraction, the blank spaces must be used to document specific risks related to low ejection fraction.
- Kindly read the consent forms thoroughly at least once. This will give you a fair idea about the scope and limitation of particular consent form.When another procedure is along with the primary surgery, one must ensure to use appropriate consent form for it. For example, in the consent form for Vaginal delivery, possible need for C- section is discussed but the consent form is not dedicated to capture consent for C section. Thus, it is necessary to use the consent form for C section, if C section is decided. Another example is C- section

with tubal ligation. In this case, two separate consent forms, one for C section and another for tubal ligation need to be used.

- Please note that the following people ought to sign on the form. Patient (guardianif minor or incapacitated), doctor (consultant/ doctor from the team), and two witnesses, one from patient's side and one from doctor's side.
- If the patient cannot sign and wants to affix thumb or if the patient does not understand the language, it will be a good idea that it is documented that she was made aware of the draft of the consent.
- Special note on consent form for vaginal delivery:

  It is not a standard practice to take consent for natural childbirth. We did brain storming on various issues related to this peculiar situation. Being Obstetricians, we know that this situation has the most unpredictable and varied outcome. So, we discussed following questions:

  - Is it necessary to create a consent form for vaginal delivery?
  - What should be the scope of this consent?
  - Should episiotomy, repair of perineal tear, instrumental delivery need a separate consent form? Should MRP need a separate consent form?
  - Is it practically possible to take such consent at an emergency hour, (For example, woman is in second stage of labour and FHR are dropping and decision for instrumental delivery is taken)?
  - When the woman is in severe pain in labour, will her consent be treated as valid consent?
  - How does one create a medicolegally protective document in this scenario?

We posed these questions to the legal wizards at the Maharashtra National Law University. These consultations have led to creation of current consent forms.

This consent form is aimed to document that the woman has received sufficient information about the process of vaginal birth that includes natural birth, perineal tears, episiotomy and instrumental deliveries. In case the doctor is doing instrumental delivery, the doctor should get the consent revalidated. Please see the end of the consent form. There is a specific mention of this revalidation.

Procedures that emerge out of the process of labour such as Emergency C section, MRP, epidural analgesia need a separate consent form. Likewise, induction of labour also needs a separate consent form.

We want to put on record that drafting consent form for vaginal delivery was the most challenging job. We request you all to give feedbacks on these so that we can improve on the next versions.

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CONSENT FOR ADMISSION IN THE HOSPITAL

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

I...aged............ years, female / male

residing at...

....

give my free, and valid consent for admission of myself / my ....(relation)

(Mr./Mrs...aged .... years residing

at...

under the treatment of Dr ....

I understand the various administrative rules and regulations of the hospital; which include but are not limited to following

- I am aware of the medical infrastructure and amenities in the various types of wards and rooms
- I understand that throughout the stay in the hospital, a responsible accompanying person will have to be available/contactable.
- I have been informed about the visiting hours for the relatives.
- I have been informed that valuables should not be carried along in the hospital premises.
- I understand that smoking and drinking alcohol is not allowed in the hospital
- I understand that there may be a need to submit photo id and residential proof of the patient within a reasonable time of admission.
- I understand that hospital is not responsible for accidents due to natural calamities or unforeseen events beyond the scope of the hospital.

- I authorise the housekeeping and other ancillary staff of the hospital to manage all relevant activities as would be needed during the stay.
- I authorise the healthcare facility to dispose specimens such as blood, tissues, secretions and organs etc obtained during the stay.

II I authorise the healthcare facility, its medical staff and paramedical staff to provide such diagnostic procedures, therapeutic procedures and treatment as in their judgement is deemed necessary in my care. Commonest procedures carried out are IV infusions, catheterisations, enema, shaving, feeding tubes etc. The procedures mentioned are indicative and not exhaustive.

III I authorise another qualified doctor to look after the continuity of treatment in case of absence of the treating doctor.

- I authorise the medical and paramedical team to reveal the healthcare record relevant to the treatment to other health care provider if deemed necessary
- I authorise the hospital authority to release the relevant healthcare record to Government agencies as and when needed.
- I authorise the hospital to release the medical record for the purpose of medical insurance and reimbursement.
- I agree to cooperate fully with the doctors and to follow instructions and recommendations and dietary advises about the care and overall treatment.
- I agree to take up the responsibility for the custody and safety of the new born that has been roomed in. (applicable for post-delivery patient)
- I confirm that I have given all the relevant details including past medical history, previous ailments, surgeries and allergies to the doctor.

IV I have been given information about the rules and regulations of the billing department of the hospital as mentioned below. The rules include but are not limited to following

- I have been made informed about the estimate of bill under various headings
- I have been made to understand that the final bill may vary from the estimate provided, as the services provided under the different headings may differ in different health related situations, which unfold on daily basis during the hospital stay.
- I understand that after the treating doctor declares that patient is to be discharged a reasonable time is needed for finalisation of the bill.
- I have been made to understand about the advance payment policy of the hospital.
- I understand that in case of medical insurance the responsibility of ensuring that claim is accepted, is with me. All relevant documents and authorisation letters will be needed to be submitted beforehand for speedy sanction of cashless claims.
- I understand that in the event that sanction letter is not received from the TPA till discharge, the bill will have to be settled in full.

V I accept that medical science is not perfect and has its limitations. No guaranty has been given about result or outcome.

VI I am aware of the grievance redressal mechanism of the hospital. I state that in case of litigation in consumer forum, an appropriate forum in whose territorial jurisdiction the hospital falls into, will be approached.

VII I hereby give a free consent willingly with sound mind, without any undue influence, coercion, fraud, misrepresentation or mistake of facts.

VIII I state that I have understood the above mentioned information fully

Sign	Sign / Thumb impression
Dr.'s Name .... Reg.no: .... Date: .... Time: .... AM / PM	Patient Name: .... Age .... years: .... Date: .... Time: .... AM / PM
Sign Name of witness .... Age .... years: .... Address .... Date: .... Time: .... AM / PM	Sign Name of witness .... Age .... years: .... Relationship with patient .... Address .... Date: .... Time: .... AM / PM

CONSENT FOR DISCHARGE AGAINST MEDICAL ADVICE

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

I...aged............ years, female / male

residing at...

....

Seek discharge of myself / my ....……..………...(relation)

(Mr./Mrs...aged .... years residing

at..

from the hospital , even when the doctor has not given discharge ....

....

I state as under:

I I state that I have understood the above mentioned information fully I have been explained the details of the present medical condition, the need to continue the treatment in the hospital and consequences and risk associated with leaving the hospital against medical advice.

II I state that I have understood the above mentioned information fully I wish to leave the hospital and take discharge even though the treating doctor has not given discharge to me.

III I state that I have understood the above mentioned information fully I have been given details about the treatment given so far and instructions and follow-up advice.

IV I state that I have understood the above mentioned information fully I have been advised not to abruptly stop the treatment but to continue the treatment at any other healthcare facility of my choice.

I declare that this decision has been made willingly with sound mind, without any undue influence, coercion, fraud, misrepresentation or mistake of facts.

V I state that I have understood the above mentioned information fully

Sign	Sign / Thumb impression
Dr.'s Name .... Reg.no: .... Date: .... Time: .... AM / PM	Patient Name: .... Age .... years: .... Date: .... Time: .... AM / PM
Sign Name of witness .... Age .... years: .... Address .... Date: .... Time: .... AM / PM	Sign Name of witness .... Age .... years: .... Relationship with patient .... Address .... Date: .... Time: .... AM / PM

CONSENT FOR DISCHARGE AT REQUEST

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

I...aged............ years, female / male

residing at...

....

request for discharge of myself / my..(relation)

(Mr./Mrs..aged .... years residing

at..

....

I declare the following

I I have been explained the details of the present medical condition, the need to be in the hospital for continued treatment and the consequences and the risk associated with leaving the hospital before fully completing the treatment and observation.

II I wish to leave the hospital and take discharge even though the treating doctor has not completed the treatment / observation/ investigations fully.

III I have been given details about the treatment given so far and instructions and follow-up advice.

IV I have been adviced not to abruptly stop the treatment but to continue the treatment as adviced.

I declare that this decision has been made willingly with sound mind, without any undue influence, coercion, fraud, misrepresentation or mistake of facts

V I state that / I have understood the above mentioned information fully (strike out whichever is not applicable

....

....

....

....

Sign	Sign / Thumb impression
Dr.'s Name .... Reg. no: .... Date: .... Time: .... AM / PM	Patient Name: .... Age .... years: .... Date: .... Time: .... AM / PM
Sign Name of witness .... Age .... years: .... Address .... Date: .... Time: .... AM / PM	Sign Name of witness .... Age .... years: .... Relationship with patient .... Address .... Date: .... Time: .... AM / PM

CONSENT FOR TRANSFER TO ANOTHER HOSPITAL

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

I..aged............. years, female / male

residing at..

....

give my free, and valid consent for transfer of myself / my ....(relation)

(Mr./Mrs...aged .... years residing

at..

to another hospital for further treatment...

I state that:

I. I have been explained about the nature of the disease of the patient.

II. I have been explained the following:

   a. Need for transfer to other hospital;

   b. Its purpose, benefits and effects;

   c. An outline of the substantial risks involved during transfer;

   d. Adverse consequences of refusing transfer.

   e. Details of other hospitals where treatment is proposed to be done.

III. I have understood that it will be prudent to continue further treatment at the other hospital hence my case is being transferred to that hospital. I have been given Information such as medical infrastructure, address, contact number, details of doctor, estimate of costs about the above mentioned hospital .

IV. I have taken informed decision to transfer to the above mentioned hospital.

V. I have been given information about the mode of transport and alternatives. I am moving the patient by the mode of transport chosen by me.

VI. I am aware that during transport limited monitoring and treatment is feasible.

VII. I have been handed over the details of treatment given so far and transfer document.

VIII. I have been encouraged to ask questions and resolve queries.

IX. After understanding all the above-mentioned information, I give free consent with sound mind, without any undue influence, coercion, fraud, misrepresentation or mistake of facts.

X. I state that I have understood the above mentioned information fully

....

....

....

....

Sign	Sign / Thumb impression
Dr.'s Name .... Reg.no: .... Date: .... Time: .... AM / PM	Patient Name: .... Age .... years: .... Date: .... Time: .... AM / PM
Sign Name of witness .... Age .... years: .... Address .... Date: .... Time: .... AM / PM	Sign Name of witness .... Age .... years: .... Relationship with patient .... Address .... Date: .... Time: .... AM / PM

HIGH RISK CONSENT

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

I..aged............ years, female / male

residing at...

....

state that myself / my ....(relation)

(Mr./Mrs...aged .... years residing

at...

is under the treatment of Dr ....

I hereby state as under:

I The doctor has explained that the patient's condition has suddenly deteriorated and is serious. The doctor has given us a brief of the further management plan.

II I have been made aware that despite all efforts there could be risk to the life of the patient.

III I have been made aware that the need to transfer the patient to intensive care unit or to other hospital may arise during the treatment.

IV I have been made to understand that the doctor may need to take steps to ensure circulation and oxygenation by emergency procedures such as endotracheal intubation, tracheostomy, Central lines, cardiopulmonary resuscitation, transfusing blood and blood products etc.

V Having understood all that is mentioned above, I give free consent to the treating doctors' team to proceed with the proposed line of treatment.

....

....

....

Sign	Sign / Thumb impression
Dr.'s Name .... Reg.no: .... Date: .... Time: .... AM / PM	Patient Name: .... Age .... years: .... Date: .... Time: .... AM / PM
Sign Name of witness .... Age .... years: .... Address .... Date: .... Time: .... AM / PM	Sign Name of witness .... Age .... years: .... Relationship with patient .... Address .... Date: .... Time: .... AM / PM

CONSENT FOR BLOOD / BLOOD PRODUCT TRANSFUSIONS

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about blood / blood products transfusion

1. **Name of the procedure:** Transfusion of blood or blood products such as packed red cells, platelets, fresh frozen plasma or cryoprecipitate.
2. **Meaning:** It is a process in which blood or blood products brought from the blood bank (or blood storage unit) is infused in the body through intravenous route as per the need.
3. **Purpose/ indications: (The list given below only indicates common reasons and does not include all indications)**

- Treatment of heavy blood loss: It is a serious condition when one loses significant amount of blood from one's body. In that case blood needs to be replenished back.
  - To treat deficiency of a specific component in the blood.
  - Due to medical condition or genetic condition, specific component of blood gets deficient. For example, in severe anemia, hemoglobin is very low and one may need to replenish red blood cells/ blood. Similarly, due to medical condition platelets may drop down and may need to be replenished. There could be some genetic conditions that cause deficiency of clotting factors. In that case these factors may need to be transfused.

  Specify if any other indication ....

4. **Description of the procedure:**

   - Blood or its products are processed in the blood bank. The blood banks test the blood for blood group, presence or absence of infective viruses or bacteria, haemoglobin etc. The blood to be transfused is then cross matched with the person receiving the blood. (Some blood products may not need cross matching.) Once the blood bank confirms that blood is suitable for transfusion and is cross matched, only then it is released by the blood bank.
   - The nurse/ doctor confirms that the blood has been certified by the blood bank.

- The nurse or doctor puts in a needle/ canula in one of the prominent veins on hands or legs or neck. If this is already done, one may use the same site for transfusing blood or blood products.
- Even after thorough check, transfusion of blood may cause reactions. Hence, the person receiving blood is watched for such reactions.

5. **Benefits & effects of the procedure**

It quickly replenishes the body's need for blood and blood products. In fact, no other medicine/ treatment can replenish the need so fast.

- **Alternatives if any:**

The doctor may use alternatives only if the need to restore the blood / deficient products is not immediate and urgent. The doctor may use medicines to stimulate the body to produce blood or its products. It is obvious that this will restore the things back slowly.

For example, Oral iron or IV iron for iron deficiency anaemia. Treatment of the cause of deficiency may be done and this may restore the condition back.

7. Consequences of refusal of the procedure:

- If blood/blood products are not transfused, especially in emergency situation, it may pose serious risk to the person's life.

8. Outline of substantial risks:

- Every donated blood sample is tested for HIV, Hepatitis B and C in the blood bank as per national regulations. In spite of careful screening there could be rare instances of acquiring infections such as HIV I & II, Hepatitis B, Hepatitis C and other viruses or diseases. Severe allergic reactions are rare. This may lead sudden drop of blood pressure and /or oxygen levels, impairment of function of heart, lungs, kidneys, shock and death.
- Minor side effects are rashes, itching, fever, chills etc

.

THIS INFORMATION LEAFLET WAS RECEIVED ON .... (date/time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

Part II: Undertaking

I.. aged...................... years, female/male/ residing at ....

....

give my free, and valid consent for the transfusion of blood and blood products to myself / my ....(relation) Mr./Mrs...aged ___ years residing at ....

....

I declare that this consent be treated as a consent for transfusions of blood and/ or blood products till the end of the hospitalisation.

I state the following

I. I/We have been explained about the nature of the disease.

II. I/We have been given the information about the transfusion procedure mentioned as follows

a. nature and procedure
b. its purpose, benefits and effect;
c. alternatives
d. an outline of the substantial risks
e. adverse consequences of refusing treatment

III. I understand that during the course of this transfusion, severe allergic reactions may occur leading to sudden collapse of vital organs. Additional treatment may be needed in such situation.

IV. I understand that in spite of careful screening in accordance with the national regulations there could be rare instances of acquiring infections such as HIV I, HIV II, Hepatitis B, Hepatitis C and other viruses.

V. I understand that the doctor/ nurse administering transfusion has no way to determine whether the blood or products will be suited or no before starting the transfusion.

VI. I accept that medical science is not perfect and has its limitations. No guaranty has been given about result or outcome.

VII. I agree to cooperate fully with my doctor and to follow instructions and recommendations about the care and overall treatment.

VIII. I confirm that all the relevant details about the patient including past medical history, previous ailments, surgeries and allergies have been given to the doctor.

IX. I/We have been encouraged to ask any question related to this Procedure/operation and had been answered well.

By signing below, I indicate that I have understood the above information (point 1 -8 & I to IX) in the language that I understand.

I give free consent willingly with sound mind, without any undue influence, coercion, fraud, misrepresentation or mistake of facts.

....

....

....

....

Sign	Sign / Thumb impression
Dr.'s Name .... Reg.no: .... Date: .... Time: .... AM / PM	Patient Name: .... Age .... years: .... Date: .... Time: .... AM / PM
Sign Name of witness .... Age .... years: .... Address .... Date: .... Time: .... AM / PM	Sign Name of witness .... Age .... years: .... Relationship with patient .... Address .... Date: .... Time: .... AM / PM

CONSENT FOR SURGERY ON BARTHOLIN'S CYST / ABCESS

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I : Information about the surgery

1. **Name of the procedure:** Bartholin cyst excision/ Bartholin abscess drainage
2. **Meaning:** The Bartholin's glands are located on either side of the vaginal opening and secrete fluid that helps in lubrication of the vagina. Sometimes the openings of these glands get blocked, causing fluid to collect into the gland. This results in a swelling near the vaginal opening and is called as Bartholin's cyst. If the fluid within the cyst becomes infected, pus may develop. This is called Bartholin's abscess.

   Non- infected small cysts may be painless; but may give rise to pain or feeling of lump near vaginal opening if size increases. Infected cyst can give rise to painful swelling, painful intercourse and fever.
3. **Purpose / indications:** To relieve the woman of the pain and discomfort, surgery is needed. Abscess needs drainage and antibiotics.
4. **Description of the procedure:** This surgery may be done under regional anaesthesia (where the lower half of the body is made numb or anaesthetised) or under general anaesthesia (where the patient is put to sleep by giving injection). A small cut is made over the cyst to drain the fluid or pus. Surgical drainage of the Bartholin's cyst with marsupialisation (stitching) of the cut edges may done or cyst may be removed completely. In case of abscess the doctor may pack the wound with antiseptic solution.
5. **Benefits & effects of the procedure:** The symptoms will disappear after successful treatment.
6. **Alternatives if any:**
   - Medical therapy: Antibiotics and pain killers may be given and at times the excision is postponed till infection settles down.
7. **Consequences of refusal of the procedure:** Woman's symptoms may increase, if size of the cyst increases. The cyst may get infected and abscess may form. This may worsen her health.

8. Outline of substantial risks:

With the advances in medical science, surgeries have become safer than in the past. However, any surgery has its own set of risks and complications.

a. Excessive bleeding/ blood accumulation: Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be rarely needed. In case the blood accumulates inside the operative site, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

b. Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

c. Injury to surrounding structures: Injury to surrounding structures such as rectum or urinary bladder is very rare in this surgery.

d. Anesthesia has become much safer in today's world. Fatal complications such as reaction to anesthetic medicine, sudden stopping of heart, fluid accumulation in the lungs are very rare but not unknown. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anesthesia. Headache after spinal and other regional anesthesia are not uncommon. Rarely weakness, numbness in lower part of the body may be caused after regional anesthesia.

e. Every Individual has a different way to cope up. Sometimes the scar becomes thick and sometimes it stays as thin line. The cyst or abscess can come up again.

f. Rare conditions: Allergic reaction to any drug, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are very rare complications of any surgery.

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(Date / Time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR HYSTEROSALPINGOGRAPHY

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

PART – 1 INFORMATION ABOUT THE PROCEDURE

1. **Name of the Procedure :** HYSTEROSALPINGOGRAPHY (HSG)

2. **Meaning:**

   A special type of X-ray test to outline the internal shape of the uterine cavity & to identify if the fallopian tubes are open

3. **Purpose/Indication of HSG**

   This test may be done as part of investigation for infertility. Infertility means inability to conceive. This test helps to doctor to understand about the cavity of the uterus and patency of fallopian tubes.

4. **Description of the procedure:**

   This procedure does not require any anesthesia. In some women anaesthesia or sedative may be needed. This test is done by using X ray machine.

   Woman is requested to lie down on x ray table with legs apart . A canula is passed through the mouth of the uterus. Through this canula, liquid dye is pushed inside the uterus. At the same time X ray is taken.

   After the procedure woman may experience cramps, pain and bleeding or discharge for few days. These can be controlled by taking prescribed medicines.

5. **Benefits of procedure:**

   This test is helpful:

   to detect abnormalities related to the cavity of the uterus.

   to detect if fallopian tubes are open

6. Alternatives

a) A surgery called hysteroscopy and laparoscopy is an alternative. In this telescope is put inside the abdominal cavity. (Chromoper Tubation)

b) The same test can also be done under sonography control. This is called as sono-salpingography (saline infusion sonography).

7. Consequenses of refusal of the procedure

If the test is not done one cannot understand if the tubes and the cavity of the uterus are normal

8. Outline of substantial risks:

With the advances in medical science, procedures have become safer than in the past. However, any procedure has its own set of risks and complications.

a. Anesthesia:

Most women do not need anesthesia for this procedure. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two in case anesthesia is used.

b. Infection:

If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. This may cause fever, pain, pus formation. The chance of infection in this procedure is very low.

c. Inability to canulate the cervix and Injury to surrounding structures:

Sometimes if the uterus is peculiarly placed in the pelvic cavity or if the cervix is too tightly closed, the doctor may not able to canulate the cervix. In that case, the doctor may have to stop the procedure and call the patient later. Injury to cervix is rare but not unknown.

d. Allergic reaction to the liquid dye may cause rashes, hives, itching, nausea, fainting or shortness of breath, syncopal attack. Additional medicines may be required.

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date/time)

Signature of the patient: ....

(INSTRUCTION TO PATIENT: PLEASE BRING THIS PAPER WHEN YOU COME TO THE HOSPITAL FOR GETTING THE SURGERY/ PROCEDURE DONE)

Part II: Undertaking

I, Miss/Mrs..., aged .... years, female residing at ....

....give my free and valid consent for myself / my ....

Miss / Mrs..aged .... years residing at ....

....

I am aware that the procedure will be carried out under the directions of ....

I am aware that anaesthesia may be administered under the instructions of Dr...

I state that

I. I have been explained about my medical condition and nature of the disease, I am suffering from

II. I have been given the information about the procedure as mentioned as above in column 1-8 and I am aware of

a. the nature of procedure,

b. its purpose, benefits and effect,

c. Available alternative if any

d. an outline of substantial risks

e. and adverse consequences of refusing treatment

III. I have been counselled about nature of anaesthesia, benefits, purpose, effects and alternatives and substantial risks

IV. I consent to observing, photographing, recording or televising of the surgery for medical, scientific or educational purpose provided my identity is not revealed by the picture or descriptive text accompanying them

V. I accept that medical science is not perfect and has its limitations. No guarantees can be given about result or outcome.

VI. I agree to cooperate fully with my doctor and to follow instructions and recommendations about my care and treatment.

VII. I confirm that I have given all the details to the doctor about myself, including past medical history including previous ailments, surgeries and allergies to any drugs

VIII. Apart from the above-mentioned general information, I have been specifically informed about individual risks related to .... (to be mentioned by doctor about any specific problems related to that patient)

IX. I was encouraged to ask any question related to this operation and had been answered well all the questions asked, way in which we could understood.

X. It was also explained that expected outcome in this treatment /procedure /operation is good/Fair/Poor

XI. I understand that I have a right to change/withdraw the consent and will inform the doctor in time (if needed)

By signing below, I indicate that I have understood the above information in language I understand

I am giving my free consent willingly with sound mind, without any undue influence, coercion, fraud, misrepresentation or mistake of facts.

I request Dr...to perform upon me the above-mentioned procedure.

.... (interpreter)has read out above mentioned to me and explained everything to me in the .... language (in case of patient giving thumb impression or not understanding language of consent printed) (This should be in vernacular language)

Sign	Sign / Thumb impression
Dr.'s Name .... Reg.no: .... Date: .... Time: .... AM / PM	Patient Name: .... Age .... years: .... Date: .... Time: .... AM / PM
Sign Name of witness .... Age .... years: .... Address .... Date: .... Time: .... AM / PM	Sign Name of witness .... Age .... years: .... Relationship with patient .... Address .... Date: .... Time: .... AM / PM

CONSENT FOR CERVICAL CIRCLAGE

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the surgery

1. **Name of the procedure: cervical cerclage**
2. **Meaning:**

   This is a surgical procedure in which a stitch is put on the cervix (opening of the uterus). It can be done vaginally or abdominally. Various types of cerclage are Mc donald's, Shirodkar and abdominal cerclage.
3. **Purpose/ indications:** (Not all but only common indications are listed below.)

   Cervix (opening of the uterus) stays closed almost till pregnancy reaches full term. It starts softening and shortening in the later part of the pregnancy. Some times the cervix starts softening/ shortening/ opening way too early. This may lead to miscarriage or preterm (premature) labour. This surgery is one of the ways to halt this process and prolong the pregnancy. If previous history indicates that the cervix may be weak, the doctor may proceed with the surgery even before the changes occur.
4. **Description of the procedure:** This surgery may be done under regional anaesthesia (where in the lower half of the body is made numb or anaesthetised) or under general anaesthesia (where the patient is put to sleep by giving injection .Most cervical cerclage procedures are done through the vagina. In some complex cases the surgery

   may be done abdominally. There are various types of cerclage surgeries. In India, MacDonald'S surgery and Shirodkar's surgery are most popular types. Your doctor will decide which one will work best for you. In this surgery a thick unabsorbable suture / tape is passed around the cervix and tied. One may need to separate the urinary bladder in some cases.

   Once the pregnancy reaches full term or if the woman goes in labour the suture is removed.

5. **Benefits of the procedure:**

A Cervical stitch may help prevent preterm births or miscarriages caused by cervical incompetence.

6. **Alternatives:**

There are three strategies to prevent miscarriage/ preterm labour due to weak cervix. Giving rest to the pregnant woman, Giving medicines to relax the uterus and doing cerclage surgery. If the surgery is not done the other two methods can always be done. It is generally considered that doing all the above gives best results.

7 **Consequences of refusal of the procedure:**

Weak cervix may lead to preterm labour/ miscarriage.

8 **Outline of substantial risks:**

With the advances in medical science, surgeries have become safer than in the past. However any surgery has its own set of risks and complications.

A. Excessive bleeding/ blood accumulation: Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

B Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional

procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon If the wound does not heal well, it may need to remove the stitches before time.

C Injury to surrounding structures and cervical laceration: While the suture/tape is being passed around the cervix, the cervix may get lacerated and/ or amniotic bag (water bag around the fetus) may get injured. The surrounding structures such as, urinary bladder,, bowel may get injured. The injury may or may not get detected immediately. Whenever detected it may need to be repaired by necessary additional surgery.

D Anaesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anaesthesia. Headache after spinal and other regional anaesthesia are not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

E Every Individual has a different way to cope up. Sometimes the suture material may cause reaction leading to chronic discharge. Some times the cervix may continue to shorten further. Some times the suture may fall off completely.

F Very rare conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, Formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery.

G Failed outcome: even with cervical cerclage there is 15% chance of preterm delivery especially cerclage done as an emergency procedure.

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date/time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR DILATATION & CURETTAGE OR DILATATION & EVACUATION OR SUCTION & EVACUATION

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the surgery

1. Name of the procedure:

Dilatation and curettage or Dilatation and evacuation or Suction evacuation.

2. Meaning

In this surgery, contents inside the uterus are removed out. Dilatation and curettage or Dilatation and evacuation or Suction evacuation are similar procedures (with minor technical differences) with same outcome or result. It is done through the vaginal route and does not involve any incision on the body.

3. Purpose/ indications: (Not all but only common indications are listed below.)

- In case of miscarriage, the procedure is done to get rid of non- viable pregnancy tissue.
- In case if woman is not desirous to continue the pregnancy and fulfils the criteria laid down under the Medical Termination of Pregnancy Act.
- If woman is bleeding heavily after delivery or miscarriage and some tissue of pregnancy is still left inside the uterus, it needs to be removed out of the uterus by doing this procedure.
- If a non-pregnant woman is bleeding very heavily, this procedure may be done to immediately reduce the blood loss.
- In case the lining of the uterus is too thick or filled with pus of fluid, the tissue/ fluid is removed and sent for further examination.
- If there is a suspicion of cancer of the uterus.
- If woman is not getting pregnant, one may need to do this procedure to find the cause.

4 Description of the procedure

This surgery may be done under general anaesthesia (where the patient is put to sleep by giving injection). It can also be done under local anaesthesia (only numbing the mouth of the uterus by injection) or regional anaesthesia (where in the lower half of the body is made numb or anaesthetised). After doing vaginal examination, the cervix (mouth or lower opening of the uterus) is held. The opening of the uterus is dilated with the help of specialised instrument. The contents of the uterus can be removed by various methods. When they are sucked out of the uterus, the procedure is called as "Suction evacuation". When they are scraped out with an instrument called curette, the procedure is called as "Dilatation and curettage". When they are removed by using mechanical device, it is called as "Dilatation and evacuation. It is common to use combination of the above methods to achieve the final goal; that is, emptying the cavity of uterus.

Few additional procedures may be done along side if woman has already expressed her desire and signed the consent form beforehand. These are insertion of Intra uterine contraceptive device or surgery to permanently stop child baring that is female sterilization or tubectomy Other procedures such as hysteroscopy (seeing the inside the uterus with a telescope) or Laparoscopy (seeing inside the abdomen), taking biopsy may also be done alongside.

5 Benefits of the procedure:

The procedure is quick, convenient and cost-effective and doesn't take much time. Usually it is done on a day care basis and overnight stay in the hospital may not be needed. This procedure helps to empty the uterus and reduce excessive bleeding. In non pregnant state, it may further help to diagnose certain conditions. The sample may be sent for detailed examination so that exact diagnosis can be ascertained.

6 Alternatives:

Endometrial aspiration using endometrial sampling cannula and syringe can be an alternative to D&C. However, it may not be as accurate.

If products of pregnancy are left inside the uterus for long time, they may cause excess bleeding, infection, pain. Hence it is better to ensure that they are removed out in timely manner. Use of medicines to contract the uterus may not be as effective as this procedure.

7 Consequences of refusal of the procedure:

It is logical to understand that if the procedure is not done, doctor may not be able to make accurate diagnosis or give treatment. This may worsen the condition.

8 Outline of substantial risks:

With the advances in medical science, surgeries have become safer than in the past. However, any surgery has its own set of risks and complications.

a. Excessive bleeding/ blood accumulation: Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

b. Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

c. Injury to surrounding structures: This procedure is a blind procedure. The doctor cannot see where the instrument is going inside the uterus. Though uncommon, the instrument may injure parts of the uterus or pass through and through the uterus and injure other structures such as urinary bladder, ureter, bowel, blood vessels. The injury may or may not get detected immediately. Whenever detected it may need to be repaired by necessary additional surgery.

d. Anesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anesthesia. Headache after spinal and other regional anesthesia is not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

e. Every Individual has a different way to cope up. Some women may experience cramps or bleed little more. Rarely, after this surgery (especially if done too often), the lining of the uterus may stick to each other or get thinned out or irritation to the tissue may lead to blocked fallopian tubes. This may interfere with menstruation and pregnancy later.

f. Very rare conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery. Rarely if the uterus is densely stuck to other organs the doctor may find it difficult to complete the procedure. In that case the doctor may resort to open or laparoscopic surgery.

g. Incomplete or no evacuation and continuation of pregnancy: It is a blind procedure. Since the doctor cannot see inside the uterus, it may so happen that the tissue is not fully removed and some of it may remain inside. This may need repeat procedure. It is rare that the instruments completely miss the pregnancy tissue and do not dislodge it

h. Inability to complete the procedure: if the cervix is tightly closed, The Doctor may not be able to negotiate it. If there is a suspicious of injury / perforation the doctor may a bond on the procedure.

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date/time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR MEDICAL TERMINATION OF PREGNANCY - MEDICAL METHOD

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the procedure:

1 Name of the procedure : Medical termination of pregnancy by medical method (using medication).

This procedure is governed by the Medical Termination of Pregnancy Act.

2. Meaning

This procedure is done when a woman desires to terminate her pregnancy. The medical method is used during early part of pregnancy. In this, woman is given some medicines. These medicines cause the uterus to contract and expel the pregnancy out.

3 Purpose/ indications: (Not all but only common indications are listed below.)

In India, medical termination of pregnancy is done in accordance with Medical Termination of Pregnancy Act. As per the law, a woman can seek termination of pregnancy if

a) The women is suffering from medical disorders (heart disease, uncontrolled blood pressures etc) and continuation of pregnancy would cause serious risk of life or physical and mental health
b) The pregnancy is the result of failure of contraception
c) The Pregnancy is caused due to rape
d) If the baby in the womb (foetus) is likely to have severe congenital abnormalities that would lead to handicap.

4 Description of the procedure

The doctor provides or prescribes medicines. The doctor explains the woman about when and how to use the medicines.

5 Benefits of the procedure:

This procedure is aimed at terminating the pregnancy as desired by the woman. This procedure does not involve any surgical procedure. The woman does not need to get admitted to the hospital.

6 Alternatives:

- Medical termination of pregnancy can also be done by surgical method. In this the woman has to go to the clinic/ hospital for few hours. She has to undergo a procedure under anaesthesia.
- Of course, the other alternative is to continue the pregnancy and give birth.

7 Consequences of refusal of the procedure:

If termination of pregnancy is not done, the pregnancy may continue to grow.

8 Outline of substantial risks:

With the advances in medical science, procedures have become safer than in the past. However, any procedure has its own set of risks and complications.

a. <u>Excessive or prolonged bleeding and /or pain:</u> The medicines make the uterus contract and expel the tissue of pregnancy out. Some women experience excessive and prolonged bleeding and pain during the process of termination. Some women may need surgical procedure to empty the uterus and stop bleeding. Rarely blood transfusion may be needed.

b. <u>Infection:</u> If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

c. <u>Incomplete evacuation or failure:</u> In spite of taking medications correctly, the uterus does not get fully emptied. Some tissue may remain inside the uterus. Four out of 100 women experience this problem. In one out of 100 cases, the medications cannot dislodge the pregnancy at all. It means that the treatment has failed.

d. <u>Every Individual</u> has a different way to cope up. Some women may experience cramps or bleed little more. Some women may experience vomiting. Fever, hyperacidity, diarrhea. These symptoms go away in few days. with / without medicine

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date / time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR MEDICAL TERMINATION OF PREGNANCY - SURGICAL METHOD (1ST TRIMESTER)

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the surgery

1 Name of the procedure : Medical termination of pregnancy by surgical method (by suction and/or curettage). This procedure is called as "suction & evacuation", "Dilatation & evacuation" or "Dilatation & curettage".

This procedure is governed by the Medical Termination of Pregnancy Act.

2. Meaning

This procedure is done when a woman desires to terminate her pregnancy. This surgical procedure is done during early part of pregnancy. In this surgery, contents inside the uterus are removed out. Dilatation and curettage or Dilatation and evacuation or Suction evacuation are similar procedures (with minor technical differences) with same outcome or result. It is done through the vaginal route and does not involve any incision on the body.

3 Purpose / indications: (Not all but only common indications are listed below.)

In India, medical termination of pregnancy is done in accordance with Medical Termination of Pregnancy Act. As per the law, a woman can seek termination of pregnancy if

a) The women is suffering from medical disorders (heart disease, uncontrolled blood pressures etc) and continuation of pregnancy would cause serious risk of life or physical and mental health

b) The pregnancy is the result of failure of contraception

c) The Pregnancy is caused due to rape

d) If the baby in the womb (foetus) is likely to have severe congenital abnormalities that would lead to handicap.

4 Description of the procedure

This surgery may be done under general anaesthesia (where the patient is put to sleep by giving injection). It can also be done under local anaesthesia (only numbing the mouth of the uterus by injection) or regional anaesthesia (where in the lower half of the body is made numb or anaesthetised). After doing vaginal examination, the cervix (mouth or lower opening of the uterus) is held. The opening of the uterus is dilated with the help of specialised instrument.The contents of the uterus can be removed by various methods. When they are sucked out of the uterus, the procedure is called as "Suction evacuation". When they are scraped out with an instrument called curette, the procedure is called as "Dilatation and curettage". When they are removed by using mechanical device, it is called as "Dilatation and evacuation. It is common to use combination of the above methods to achieve the final goal; that is emptying the cavity of uterus.

If woman has already expressed her desire and signed the consent form before hand few procedures may be done alongside. These are insertion of Intra uterine contraceptive device or surgery to permanently stop child baring that is female sterilization or tubalization

5 Benefits of the procedure:

This procedure is aimed at terminating the pregnancy as desired by the woman. This procedure does not involve any surgical cut. It is done vaginally. The woman recovers fast and usually overnight stay in the hospital is not needed.

6 Alternatives:

- Medical termination of pregnancy using medicines (medical method): MTP can also be done by giving some medications. But medications work only if pregnancy is very small. Medications can lead to excessive bleeding, pain, cramps, diarrhoea, fever. Importantly medical method also has small percentage of failure rate.
- Of course, the other alternative is to continue the pregnancy and give birth.

7 Consequences of refusal of the procedure:

If termination of pregnancy is not done, the pregnancy can continue to grow.

8 Outline of substantial risks:

With the advances in medical science, surgeries have become safer than in the past. However, any surgery has its own set of risks and complications.

a. Excessive bleeding/ blood accumulation: Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

b. Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

c. Injury to surrounding structures: This procedure is a blind procedure. The doctor cannot see where the instrument is going inside the uterus. Though uncommon, the instrument may injure parts of the uterus or pass through and through the uterus and injure other structures such as urinary bladder, ureter, bowel, blood vessels. The injury may or may not get detected immediately. Whenever detected it may need to be repaired by necessary additional surgery.

d. Anesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anesthesia. Headache after spinal and other regional anesthesia is not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia

.

e. Every Individual has a different way to cope up. Some women may experience cramps or bleed little more. Rarely, after this surgery (especially if done too often), the lining of the uterus may stick to each other or get thinned out or irritation to the tissue may lead to blocked fallopian tubes. This may interfere with menstruation and pregnancy later.

f. Very rare conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery.

g. Incomplete or no evacuation and continuation of pregnancy: It is a blind procedure. Since the doctor cannot see inside the uterus, it may so happen that the tissue is not fully removed and some of it may remain inside. This may need repeat procedure. It is rare that the instruments completely miss the pregnancy tissue and don't dislodge it at all! This may lead to continuation of pregnancy.

h. Inability to complete the procedure: if the cervix is tightly closed, The Doctor may not b e able to negotiate it. If there is a suspicious of injury / perforation the doctor may abondon the procedure.

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date / time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR ABDOMINAL HYSTERECTOMY

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the surgery

1. **Name of the procedure: open/ abdominal hysterectomy. Additionally, following procedures may be done:**

   Salpingectomy: Right / left / both

   Ovarian cystectomy: Right / left / both

   Oophorectomy: Right / left / both

   (Tick mark what is applicable / strike out what is not applicable)

2. **Meaning:** Surgical removal of the uterus is called hysterectomy. Uterus along with its lower part (cervix) is removed in this case. In some cases, the cervix is not removed. Along with the uterus, ovary (or both ovaries) and/ or fallopian tube (or both fallopian tubes) may also be removed. Removal of ovary is called oophorectomy and removal of fallopian tube is called salpingectomy. Sometimes ovaries may have abnormal growths called "ovarian cysts". Removal of cysts is called as "ovarian cystectomy." When the surgery is performed by making an incision on the abdomen, it is called as open or abdominal hysterectomy.

3. **Purpose/ indications: (The list given below only indicates common reasons and does not include all indications):**

   I. Heavy and irregular bleeding from the uterus not responding to medical treatment.

   II. Fibroids of the uterus: Mostly fibroids cause excessive bleeding, anaemia, pelvic pain and symptoms related to pressure on adjacent organs.

   III. Uterus which has descended from its place. This is called prolapse.

IV. Endometriosis and adenomyosis/ adenomyoma

V. Cancer involving genital tract or other organs

VI. Certain types of Endometrial hyperplasia.(meaning thickening of the inner lining of the uterus)

VII. Chronic pain caused due to uterus

VIII. Any other condition: ____ ____ (for manual entry)

4. Description of the procedure: This surgery may be done under regional anaesthesia (where in the lower half of the body is made numb or anaesthetised) or under general anaesthesia (where the patient is put to sleep by giving injection). The doctor makes an incision on the abdomen. The uterus is separated from the urinary bladder and the rectum. The uterus is disconnected from all the supports and blood vessels. Thus the uterus is free and is removed from the body. In case if the ovary, ovarian cyst and/ or fallopian tube is to be removed, it is also separated from other structures, blood vessels are tied and the part is removed.

5. Benefits & effects of the procedure :

The diseased uterus is responsible directly for the medical condition and the suffering. Thus, removal of the uterus means removal of the root cause in itself.

After undergoing this surgery, menstruation stops permanently. The woman will not be able to become pregnant after this surgery. Woman can resume all other activities including sexual intercourse after recovering from the surgery.

Effects of removal of the ovaries: As ovary/ ovaries are removed there is no chance that woman will suffer from the disease of ovary in future life. If both ovaries are removed, the secretion of female hormones will cease completely. In some women, this may lead to symptoms of hormone deficiency such as hot flushes, bone pain, bone weakness, weight gain, hair loss, vaginal dryness. If woman is nearing menopause the hormonal secretion, in any case, may be very low. Thus removal of ovaries may not cause so much of disturbances. Medicines may be prescribed by the doctor to deal with these symptoms.

Effects of removal of cyst of ovary: If ovary is showing an abnormal growth such as cyst, the doctor may remove the cyst. Thus, normal tissue of the ovary is retained and only cyst is removed. Thus, ovary continues to do its job of producing hormones.

Removal of fallopian tube/tubes: The chance of fallopian tube getting diseased in future is eliminated when the tube is removed. There is some scientific evidence that cancer of ovary originates in the later part of the tube. Thus removal of fallopian tube may provide protection from possibility of ovarian cancer in future. However more studies are being done to prove this.

6. Alternatives:

- **Medical therapy:**

  If woman is suffering from excessive and / or irregular bleeding, hormonal or non-hormonal medicines can be given to her. There can be oral medicines or injections. Hormones can be delivered by a device fitted in the uterus.

- **Other surgical procedures:**

  In recent years new techniques have been developed where by the lining of the uterus is burnt or removed by surgical procedures. There is a possibility that symptoms may recur or one may not respond to the treatment.

  In case of fibroids, only fibroids may be removed. This is called “myomectomy”. However, there is a possibility that new fibroids may get formed in the uterus during later life. This will again cause trouble and recurrence of symptoms and may again need a surgery in later life. Typically, those who want to preserve the menstruation and child bearing may opt for this alternative.

  In case of endometriosis or adenomyoma, only diseased tissue may be removed. Yet again there is a possibility of recurrence.

- **Other modes of hysterectomy:**

  Once it is decided to remove the uterus, it is important to understand the ways to d o the surgery. The hysterectomy can be done by making a surgical cut on the abdomen or through the birth passage (vagina) or by using laparoscopy.

  When uterus is removed via birth passage, there are no incisions on the abdomen. If the uterus is high up in the pelvis or large in size, this method of operating through vagina may not be suitable. In laparoscopic surgery there are multiple small incisions made on the abdomen. But all cases may not be suitable for laparoscopy. Especially if fibroids are very large or peculiarly placed or if there have been previous surgeries on the abdomen, laparoscopic surgery may be difficult.

  Abdominal surgery is conventional surgery, doesn't need high tech equipment and is relatively less complex in nature. The surgeon gets relatively easy access to the tissues. These are the advantages of open surgery over other modes of surgery.

7. Consequences of refusal of the procedure:

If surgery is not done, woman may need to choose other alternative modalities as discussed above.

If no treatment is done, woman may not get any relief from the suffering.

8. Outline of substantial risks:

With the advances in medical science, surgeries have become safer than in the past. However any surgery has its own set of risks and complications.

a. <u>Excessive bleeding/ blood accumulation:</u> Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

b. <u>Infection:</u> If the microorganisms from the outside enter the body and are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional doses of antibiotics and sometimes additional procedure may be required to remove the .

infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon

c. Injury to surrounding structures: While the uterus is being separated from the surrounding structures such as urinary bladder, ureter, bowel, blood vessels may get injured. The injury may or may not get detected immediately. Whenever detected it need to be repaired by necessary additional surgery.

d. Anesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anesthesia. Headache after spinal and other regional anesthesia is not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

e. Every Individual has a different way to cope up. Sometimes the scar becomes thick and some- times it stays as a thin line. Some- times hernia formation may occur later. In some cases surgery leads to adhesions of bowel. In later life, if the supports around the vagina get loosened, the vagina may prolapse partly or fully.

f Very rare conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery. Rarely if the uterus is densely stuck to other organs the doctor may find it difficult to complete the procedure.

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date / time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR VAGINAL HYSTERECTOMY

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the surgery

1. **Name of the procedure: Vaginal hysterectomy. Additionally, following procedures may be done:**

Salpingectomy: Right/ left / both

Ovarian cystectomy: Right/ left/ both

Oophorectomy: Right/ left/ both

(Tick mark what is applicable/ strike out what is not applicable)

2. **Meaning:** Surgical removal of the uterus is called hysterectomy. Uterus along with its lower part (cervix) is removed in this case. Along with the uterus, ovary (or both ovaries) and/ or fallopian tube (or both fallopian tubes) may also be removed. Removal of ovary is called oophorectomy and removal of fallopian tube is called salpingectomy. Sometimes ovaries may have abnormal growths called "ovarian cysts". Removal of cysts is called as "ovarian cystectomy." When the surgery is performed by making an incision through natural body opening of vagina it is called as vaginal hysterectomy.

3. **Purpose/ indications: (The list given below only indicates common reasons and does not include all indications):**
    I. Heavy and irregular bleeding from the uterus not responding to medical treatment.
    II. Fibroids of the uterus: Mostly fibroids cause excessive bleeding, anaemia, pelvic pain and symptoms related to pressure on adjacent organs.

III. Uterus which has descended from its place. This is called prolapse.

IV. Endometriosis and adenomyosis/ adenomyoma

V. Cancer involving genital tract or other organs

VI. Certain types of Endometrial hyperplasia. (meaning thickening of the inner lining of the uterus)

VII. Chronic pain caused due to uterus

VIII. Any other condition: ____

(for manual entry)

4. **Description of the procedure:** This surgery may be done under regional anaesthesia (where in the lower half of the body is made numb or anaesthetised) or under general anaesthesia (where the patient is put to sleep by giving injection). The doctor makes an incision through the vagina. The uterus is separated from the urinary bladder and the rectum. The uterus is disconnected from all the supports and blood vessels. Thus, the uterus is made free and is removed from the body. In case, if the ovary, ovarian cyst and/ or fallopian tube is to be removed, it is also separated from surrounding structures, blood vessels are tied and the part is removed. During the surgery, if there is any difficulty in proceeding with the surgery through vagina, Laparoscopy or open surgery is done to complete the procedure.

5. **Benefits & effects of the procedure:**

The diseased uterus is responsible directly for the medical condition and the suffering. Thus, removal of the uterus means removal of the root cause in itself.

After undergoing this surgery, menstruation stops permanently. The woman will not be able to become pregnant after this surgery. Woman can resume all other activities including sexual intercourse after recovering from the surgery.

Effects of removal of the ovaries:_ As ovary/ ovaries are removed there is no chance that woman will suffer from the disease of ovary in future life. If both ovaries are removed, the secretion of female hormones will cease completely. In some women, this may lead to symptoms of hormone deficiency such as hot flushes, back pain, bone weakness, weight gain, dryness in vagina area. If woman is nearing menopause, the hormonal secretion, in any case, may be very low. Thus, removal of ovaries may not cause so much of disturbances. Medicines may be prescribed by the doctor to deal with the symptoms.

Effects of removal of cyst of ovary: If ovary is showing an abnormal growth such as cyst, the doctor may remove the cyst. Thus, normal tissue of the ovary is retained and only cyst is removed. Thus, ovary continues to do its job of producing hormones.

Removal of fallopian tube / tubes: The chance of fallopian tube getting diseased in future is eliminated when the tube is removed. There is some scientific evidence that cancer of ovary originates in the later part of the tube. Thus, removal of fallopian tube may provide protection from possibility of ovarian cancer in future. However more studies are being done to prove this. During Vaginal Surgery, it may not be possible to remove tubes and / or oraries

6 Alternatives:

- **Medical therapy:**

If woman is suffering from excessive and / or irregular bleeding, hormonal or non-hormonal medicines can be given to her. There can be oral medicines or injections. Hormones can be delivered by a device fitted in the uterus.

- **Other surgical procedures:**

In recent years new techniques have been developed where by the lining of the uterus is burnt or removed by surgical procedures. There is a possibility that symptoms may recur or one may not respond to the treatment.

In case of fibroids, only fibroids may be removed. This is called "myomectomy". However, there is a possibility that new fibroids may get formed in the uterus during later life. This will again cause trouble and recurrence of symptoms and may again need a surgery in later life. Typically, those who want to preserve the menstruation and child bearing may opt for this alternative. Removal of Fibroid through vagina can be done only if fibroid is low place or coming out of the cervix

In case of endometriosis or adenomyoma, only diseased tissue may be removed. Yet again there is a possibility of recurrence.

- **Other modes of hysterectomy:**

Once it is decided to remove the uterus, it is important to understand the ways to do the surgery. The hysterectomy can be done by making a surgical cut on the abdomen or through the birth passage or vagina or by using laparoscopy.

In laparoscopic surgery there are multiple small incisions made on the abdomen. In abdominal or open surgery, a long cut is needed to be made on the abdomen.

When uterus is removed via birth passage, there are no incisions on the abdomen. The recovery is very fast. These are the advantages of this method. The chance of injury to urinary bladder or ureter is least in this method. Over all, this method of surgery is considered to be the least invasive method of hysterectomy.

7. Consequences of refusal of the procedure:

If surgery is not done, woman may need to choose other alternative modalities as discussed above. If no treatment is done, woman may not get any relief from the suffering.

8. O utline of substantial risks:

With the advances in medical science, surgeries have become safer than in the past. However, any surgery has its own set of risks and complications.

a. Excessive bleeding/ blood accumulation: Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

b. Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

c. Injury to surrounding structures: While the uterus is being separated from the surrounding structures such as urinary bladder, ureter, bowel, blood vessels may get injured. The injury may or may not get detected immediately. Whenever detected it may need to be repaired by necessary additional surgery.

d. Anesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anesthesia. Headache after spinal and other regional anesthesia is not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

e. Every Individual has a different way to cope up. Sometimes the scar becomes thick and sometimes it stays as a thin line. Sometimes hernia formation may occur later. In some cases, surgery leads to adhesions of bowel. In later life, if the supports around the vagina get loosened, the vagina may prolapse partly or fully.

f. Very rare conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown

complications of any surgery. Rarely if the uterus is densely stuck to other organs the doctor may find it difficult to complete the procedure. In that case the doctor may resort to open or laparoscopic surgery.

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date / time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR LAPROSCOPIC HYSTERECTOMY

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I : Information about the surgery

1. **Name of the procedure: Laparoscopic hysterectomy.**

   Additionally, following procedures may be done:

   Salpingectomy: Right / left / both

   Ovarian cystectomy: Right / left / both

   Oophorectomy: Right / left / both

   (Tick mark what is applicable / strike out what is not applicable)

2. **Meaning:** Surgical removal of the uterus is called hysterectomy. Uterus along with its lower part (cervix) is removed in this case. In some cases, the cervix is not removed. Along with the uterus, ovary (or both ovaries) and/ or fallopian tube (or both fallopian tubes) may also be removed. Removal of ovary is called oophorectomy and removal of fallopian tube is called salpingectomy. Sometimes ovaries may have abnormal growths called "ovarian cysts". Removal of cysts is called as "ovarian cystectomy." When the surgery is performed by using a telescope and other instruments by making small incisions on the abdomen, it is called as laparoscopic hysterectomy.

   <u>Purpose/ indications:</u> (The list given below only indicates common reasons and does not include all indications):

   I. Heavy and irregular bleeding from the uterus not responding to medical treatment.

   II. Fibroids of the uterus: Mostly fibroids cause excessive bleeding, anaemia, pelvic pain and symptoms related to pressure on adjacent organs.

   III. Uterus which has descended from its place. This is called prolapse.

   IV. Endometriosis and adenomyosis/ adenomyoma

   V. Cancer involving genital tract or other organs

VI. Certain types of Endometrial hyperplasia.(meaning thickening of the inner lining of the uterus)

VII. Chronic pain caused due to uterus

VIII. Any other condition:

____

______________________________ (for manual entry)

3. Description of the procedure: This surgery may be done under regional anaesthesia (where in the lower half of the body is made numb or anaesthetised) or under general anaesthesia (where the patient is put to sleep by giving injection). The doctor makes multiple small incisions on the abdomen. Gas (carbon dioxide or air) is filled with a specialised gadget in the abdomen. Using specialised energy devices, the uterus is separated from the urinary bladder and the rectum. It is disconnected from all the supports and blood vessels. Thus, the uterus is free and is removed from the body. In case if the ovary, ovarian cyst and/ or fallopian tube is to be removed, it is also separated from other structures, blood vessels are tied and the part is removed. The doctor may complete the separation and removal of the uterus by laparoscopy fully and part of the procedure may be done through vagina.

4. Benefits & effects of the procedure :

The diseased uterus is responsible directly for the medical condition and the suffering. Thus, removal of uterus means removal of the root cause in itself. After undergoing this surgery menstruation stops permanently. The woman will not be able to become pregnant after this surgery. Woman can resume all other activities including sexual intercourse after recovering from the surgery.

Effects of removal of the ovaries: As ovary/ ovaries are removed there is no chance that woman will suffer from the disease of ovary in future life. If both ovaries are removed, the secretion of female hormones will cease completely. In some women, this may lead to symptoms of hormone deficiency such as hot flushes, bone pain, bone weakness, weight gain, hair loss, vaginal dryness. If woman is nearing menopause the hormonal secretion, in any case, may be very low. Thus removal of ovaries may not cause so much of disturbances. Medicines may be prescribed by the doctor to deal with these symptoms.

Effects of removal of cyst of ovary: If ovary is showing an abnormal growth such as cyst, the doctor may remove the cyst. Thus, normal tissue of the ovary is retained and only cyst is removed. Thus, ovary continues to do its job of producing hormones.

Removal of fallopian tube/tubes: The chance of fallopian tube getting diseased in future is eliminated when the tube is removed. There is some scientific evidence that cancer of ovary originates in the later part of the tube. Thus removal of fallopian tube may provide protection from possibility of ovarian cancer in future. However more studies are being done to prove this.

5. Alternatives:

- **Medical therapy:**

  If woman is suffering from excessive and / or irregular bleeding, hormonal or non-hormonal medicines can be given to her. There can be oral medicines or injections. Hormones can be delivered by a device fitted in the uterus.

- **Other surgical procedures:**

  In recent years new techniques have been developed where by the lining of the uterus is burnt or removed by surgical procedures. There is a possibility that symptoms may recur or one may not respond to the treatment.

  In case of fibroids, only fibroids may be removed. This is called “myomectomy”. However, there is a possibility that new fibroids may get formed in the uterus during later life. This will again cause trouble and recurrence of symptoms and may again need a surgery in later life. Typically, those who want to preserve the menstruation and child bearing may opt for this alternative.

  In case of endometriosis or adenomyoma, only diseased tissue may be removed. Yet again there is a possibility of recurrence.

- **Other modes of hysterectomy:**

  Once it is decided to remove the uterus, it is important to understand the ways to do the surgery. The hysterectomy can be done by making a surgical cut on the abdomen or through the birth passage or vagina or by using laparoscopy.

When uterus is removed via birth passage, there are no incisions on the abdomen. If the uterus is high up in the pelvis or large in size, this method of operating through vagina may not be suitable. Abdominal surgery is conventional surgery, doesn't need high tech equipment and is relatively less complex in nature. But it needs sufficient incision (transverse or vertical) on the abdomen.

Laparoscopic surgery involves multiple but small incisions and hence is more cosmetic in nature. These are the advantages of laparoscopic surgery over other modes of surgery.

7. Consequences of refusal of the procedure:

If surgery is not done, woman may need to choose other alternative modalities as discussed above. If no treatment is done, woman may not get any relief from the suffering.

8. Outline of substantial risks:

With the advances in medical science, surgeries have become safer than in the past. However any surgery has its own set of risks and complications.

a. Excessive bleeding/ blood accumulation: Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

b. Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

c. Injury to surrounding structures: While the uterus is being separated from the surrounding structures such as urinary bladder, ureter, bowel blood vessels may get injured. The injury may or may not get detected immediately. Use of electricity and heat may cause injury to surrounding structures which may become evident later. Whenever detected it may need to be repaired by necessary additional surgery.

d. Anesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anesthesia. Headache after spinal and other regional anesthesia is not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

e. Every Individual has a different way to cope up. Sometimes the scar becomes thick and some- times it stays as a thin line. Some- times hernia formation may occur later. In some cases surgery leads to adhesions of bowel. In later life, if the supports around the vagina get loosened, the vagina may prolapse partly or fully.

f. Very rare- conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery. Rarely if the uterus is densely stuck to other organs the doctor may find it difficult to complete the procedure. In that case the doctor may resort to open surgery.

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Signature of the patient: ....

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CONSENT FOR DIAGNOSTIC HYSTEROSCOPY

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the surgery

1. **Name of the procedure: Hysteroscopy- Diagnostic.**

2. **Meaning:** Female reproductive system consists of uterus, two ovaries and two fallopian tubes. Hysteroscopy means use of telescope to see the inside of uterus. The doctor introduces telescope through vagina. No incision is needed on the abdomen. The doctor gets to see the lining of the uterus and the opening of the fallopian tubes. Doctor may also take biopsies of tissues to confirm certain conditions.

3. **Purpose/ indications:** (The list given below only indicates common reasons and does not include all indications):

   I. To find out the cause of infertility: When woman is not getting pregnant, the doctor may need to examine the uterus to find out the reason.
   II. To find out the cause of abnormal uterine bleeding.
   III. To diagnose or rule out infections inside the uterus such as tuberculosis.
   IV. To rule out or diagnose malignancy or its progression.
   V. To diagnose any structural abnormality in the uterus.
   VI. To aide surgeries done through laparoscopy
   VII. To diagnose presence of tumours, growths like fibroids, foreign body (such as missed contraceptive devices), adhesions.
   VIII. Any other condition: ____
   ____(for manual entry)

4 **Description of the procedure:** This surgery may be done under regional anaesthesia (where in the lower half of the body is made numb or anaesthetised) or under general anaesthesia (where the patient is put to sleep by giving injection) or local anaesthesia.

In Hysteroscopy, the doctor widens the mouth of the uterus using instruments called dilators. A thin telescope is put inside the uterus. The uterus is filled up with fluid (saline or other specialised fluids). The doctor sees the structures through the telescope. In certain cases, the doctor can take a biopsy of the tissue.

5. Benefits & effects of the procedure:

Direct visualisation of the inside of the uterus helps in the diagnosis. As no incision is taken, recovery is very fast.

6. Alternatives:

Sonography, MRI, X-ray can be used to make diagnosis.

7. Consequences of refusal of the procedure:

If surgery is not done, one may not be able to make or confirm the diagnosis hence treatment cannot be initiated.

8. Outline of substantial risks:

With the advances in medical science, surgeries have become safer than in the past. However, any surgery has its own set of risks and complications.

a Excessive bleeding/ blood accumulation: Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

b. Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

c. Injury to surrounding structures: Dilatation of the cervix is a blind procedure. At this time, the uterus may perforate or the dilator may not enter into the cavity that is to be examined. During the surgery various organs in the abdominal cavity such as urinary bladder, ureter, bowel, major blood vessels may get injured. The injury may or may not get detected immediately. Whenever detected it need to be repaired by necessary additional surgery. Rarely the doctor may have to abandon the procedure.

d. Anaesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anaesthesia. Headache after spinal and other regional anaesthesia are not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

e. Very rare- conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery.

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Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR DIAGNOSTIC+OPERATIVE HYSTEROSCOPY

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the surgery

1. **Name of the procedure: Hysteroscopy- Diagnostic+ Operative (if needed)**
2. **Meaning:** Female reproductive system consists of uterus, two ovaries and two fallopian tubes. Hysteroscopy means use of telescope to see the inside of uterus. Hysteroscopy means use of telescope to see the inside of uterus. The doctor introduces telescope through vagina. No incision is needed on the abdomen. The doctor gets to see the lining of the uterus and the opening of the fallopian tubes. Doctor may also take biopsies of tissues to confirm certain conditions. Once the doctor makes a diagnosis, the doctor may proceed to treat or correct the abnormalities found at the same sitting. All abnormal findings cannot be dealt with at the same time. These may need to be treated at later date.

3. **Purpose/ indications: (The list given below only indicates common reasons and does not include all indications):**

I. To find out the cause of infertility: When woman is not getting pregnant, the doctor may need to examine the uterus to find out the reason.

II. To find out the cause of abnormal uterine bleeding.

III. To diagnose or rule out infections inside the uterus such as tuberculosis.

IV. To rule out or diagnose malignancy or its progression.

V. To diagnose any structural abnormality in the uterus.

VI. To aide surgeries done through laparoscopy

VII. To diagnose presence of tumours, growths like fibroids, foreign body (such as missed contraceptive devices), adhesions.

VIII. Any other condition:____

____________________________________ (for manual entry)

4. Description of the procedure: This surgery may be done under regional anaesthesia (where in the lower half of the body is made numb or anaesthetised) or under general anaesthesia (where the patient is put to sleep by giving injection) or local anaesthesia. In Hysteroscopy, the doctor widens the mouth of the uterus using instruments called dilators. A thin telescope is put inside the uterus. The uterus is filled up with fluid (saline or other specialised fluids). The doctor sees the structures through the telescope. If the doctor finds an abnormality that needs surgical treatment the doctor may proceed and treat such conditions. Common conditions that may be treated alongside are as under (List below is indicative):

5. Benefits & effects of the procedure:

Direct visualisation of the inside or the uterus helps in diagnosis. As no incision is taken, recovery is very fast. As the doctor treats the condition at the same sitting, another surgery at a later date is avoided.

6. Alternatives:

Sonography, MRI, X-ray can be used to make diagnosis.

7. Consequences of refusal of the procedure:

If surgery is not done, one may not be able to make or confirm the diagnosis hence treatment

8. Outline of substantial risks:

With the advances in medical science, surgeries have become safer than in the past. However, any surgery has its own set of risks and complications.

a. Excessive bleeding/ blood accumulation: Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

b. Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional

procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

c. Injury to surrounding structures: Dilatation of the cervix is a blind procedure. At this time, the uterus may perforate or the dilator may not enter into the cavity that is to be examined. During the surgery various organs in the abdominal cavity such as urinary bladder, ureter, bowel, major blood vessels may get injured. The injury may or may not get detected immediately. Whenever detected it need to be repaired by necessary additional surgery. Rarely the doctor may have to abandon the procedure.

d. Anaesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anaesthesia. Headache after spinal and other regional anaesthesia are not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

Very rare- conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery.

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date/time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR LAPROSCOPIC TUBAL LIGATION

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the surgery

1. **Name of the procedure:** Laparoscopic tubal sterilization. This is also called as laparoscopic tubectomy or laparoscopic tubal ligation.

2. **Meaning:** Female reproductive system consists of uterus, right and left ovaries and right and left fallopian tubes. These fallopian tubes carry egg and sperm towards each other leading to pregnancy. When these tubes are blocked by surgical technique, it is called as tubal sterilization. When this surgery is performed by using a telescope, it is called as laparoscopic sterilization.

3. **Purpose/ indications:**

The only purpose of this surgery is to ensure permanent contraception. A woman will not be able to conceive naturally after this surgery. Only those women who are sure that they do not want to get pregnant in later life and also do not wish to use any other form of contraceptive should prefer to undergo this surgery.

4. **Description of the procedure:** This surgery may be done under local anaesthesia (where skin is made numb by giving injection.) or under general anaesthesia (where the patient is put to sleep by giving injection). In Laparoscopy the doctor makes multiple small incisions on the abdomen. A telescope is put inside the abdomen. The doctor sees the structures through the telescope. The abdomen is filled up with a gas (carbon dioxide or air). The doctor operates using specialised instruments. The uterus is identified. Fallopian tube on each side is identified. The tubes may be blocked by various methods. A commonly used method is to apply elastic bands on the both the tubes and block them. This procedure may be done within few days after the menstrual cycle. This procedure can be done along with medical termination of pregnancy and other surgeries.

5. Benefits & effects of the procedure:

As both fallopian tubes are blocked the sperm will not be reach the egg and fertilise it. This provides permanent contraception and the woman does not need to use any other contraceptive after this surgery. This surgery does not affect menstruation, sexual activity or any other hormonal secretions. However, this surgery does not protect the woman and her partner from sexually transmitted diseases. If a woman wants to become pregnant after this surgery, she needs to undergo another surgery to reverse the effects. She may also choose to use artificial reproductive technologies such as In Vitro Fertilization (IVF).

6. Alternatives:

- **Use of other contraceptive methods:**

  Natural methods of contraction such as avoiding intercourse on certain days or avoiding to ejaculate inside the vagina have been found to be quite inaccurate. Hence it is advisable that woman uses one of the contraceptives such as condoms, oral contraceptive pills, injectable contraceptives or devices like copper T etc.

- **Male contraceptive:**

  The partner may undergo vasectomy which is a permanent surgical method for male contraception. This method is safe and effective permanent contraceptive.

7. Consequences of refusal of the procedure:

If surgery is not done, woman needs to use some other method of contraception. If she does not use any contraceptive, she may get pregnant due to unprotected intercourse.

8. Outline of substantial risks:

With the advances in medical science, surgeries have become safer than in the past. However, any surgery has its own set of risks and complications.

a. Failure: Although this method is a permanent method, there is a risk of failure. The chance of failure is extremely low and is estimated to be around 0.5%. It is important that if woman misses her menstrual cycle, she should rule out pregnancy. The pregnancy may get placed in the uterus or outside the uterus. Pregnancy outside the uterus is called as “Ectopic pregnancy”.

b. Excessive bleeding/ blood accumulation: Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

c. Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

d. Injury to surrounding structures: While the fallopian tube is being identified, the surrounding structures such as uterus, ovary, urinary bladder, ureter, bowel, blood vessels may get injured. The injury may or may not get detected immediately. Whenever detected it may need to be repaired by necessary additional surgery.

e. Anesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anesthesia. Headache after spinal and other regional anesthesia is not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

f. Every Individual has a different way to cope up. Sometimes the scar becomes thick and some- times it stays as thin line. Some- times hernia formation may occur later. In some cases, surgery leads to adhesions of bowel.

g. Very rare conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery.

h. Inability to reach the fallopian tube/s: If the fallopian tubes are badly stuck to other organs in the abdomen, the doctor may not be able to identify the fallopian tubes separately and tie them.

This is more common with women who have had previous surgeries or infections or with women who are obese. In such a case, the doctor may decide to do open surgery or may prefer to abandon the procedure at that time.

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date/time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR ABDOMINAL TUBAL LIGATION

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the surgery

1. **Name of the procedure:** open/ abdominal tubal sterilization. This is also called tubectomy or tubal ligation.
2. **Meaning:** Female reproductive system consists of uterus, right and left ovaries and right and left fallopian tubes. These fallopian tubes carry egg and sperm towards each other leading to pregnancy. When these tubes are blocked by surgical technique it is called as tubal sterilization. When this surgery is performed by making an incision on the abdomen, it is called as open or abdominal tubal ligation.
3. **Purpose/ indications:**

   The only purpose of this surgery is to ensure permanent contraception. A woman will not be able to conceive naturally after this surgery. Only those women who are sure that they do not want to get pregnant ever in later life and also do not wish to use any other form of contraceptive should prefer to undergo this surgery.
4. **Description of the procedure:** This surgery may be done under regional anaesthesia (where in the lower half of the body is made numb or anaesthetised) or under general anaesthesia (where the patient is put to sleep by giving injection) or local anasthesia. The doctor makes a small incision on the abdomen. The uterus is identified. Fallopian tube on each side is identified. The tubes may be blocked by various methods. A commonly used method is to tie or ligate the tube and cut off the mid portion of the tube. This procedure may be done within few days after delivery (post- partum tubal ligation) or after the menstrual cycle (Interval tubal ligation).This procedure can be done along with caesarean operation, medical termination of pregnancy and few other surgeries.

5. Benefits & effects of the procedure:

As both fallopian tubes are blocked, the sperm will not reach the egg and fertilise it. This provides permanent contraception and the woman does not need to use any other contraceptive after this surgery. This surgery does not affect menstruation, sexual activity or any other hormonal secretions. However, this surgery does not protect the woman and her partner from sexually transmitted diseases. If a woman wants to become pregnant after this surgery, she needs to undergo another surgery to reverse the effects. She may also choose to use artificial reproductive technologies such as In Vitro Fertilization (IVF).

6. Alternatives:

- **Use of other contraceptive methods:**
- Natural methods of contraction such as avoiding intercourse on certain days or avoiding to ejaculate inside the vagina have been found to be quite inaccurate Hence it is advisable that woman uses one of the contraceptives such as condoms, oral contraceptive pills, injectable contraceptives or devices like copper T etc.
- Male contraceptive:

  The partner may undergo vasectomy which is a permanent surgical method for male contraception. This method is safe and effective permanent contraceptive.

7. Consequences of refusal of the procedure:

If surgery is not done, woman needs to use some other method of contraception. If she does not use any contraceptive, she may get pregnant due to unprotected intercourse.

8. Outline of substantial risks:

With the advances in medical science, surgeries have become safer than in the past. However, any surgery has its own set of risks and complications.

a. Failure: Although this method is a permanent method, there is a risk of failure. The chance of failure is extremely low and is estimated to be around 0.5%. It is important that if woman misses her menstrual cycle, she should rule out pregnancy. The pregnancy may get placed in the uterus or outside the uterus. Pregnancy outside the uterus is called as "Ectopic pregnancy".

b. Excessive bleeding/ blood accumulation: Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

c. Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

d. Injury to surrounding structures: While the fallopian tube is being identified, the surrounding structures such as uturus ovary, urinary bladder, ureter, bowel, blood vessels may get injured. The injury may or may not get detected immediately. Whenever detected it may need to be repaired by necessary additional surgery.

e. Anesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anesthesia. Headache after spinal and other regional anesthesia is not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

f. Every Individual has a different way to cope up. Sometimes the scar becomes thick and some- times it stays as thin line. Some- times hernia formation may occur later. In some cases, surgery leads to adhesions of bowel.

g. Very rare conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery.

h. Inability to reach the fallopian tube/s: If the fallopian tubes are badly stuck to other organs in the abdomen, the doctor may not be able to identify the fallopian tubes separately and tie them. This is more common with women who have had previous surgeries or infections or with women who are obese. In such a case, the doctor may decide to abandon the procedure at that time.

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date/time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR OVARIAN CYSTECTOMY OR OOPHORECTOMY OR SALPINGECTOMY

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the surgery

1. **Name of the procedure:Laparotomy for**

- **Ovarian/ adnexal cystectomy: Ovarian / adnexal cystright/ left/ both**
- **Oophorectomy: right/left/ both**
- **Salpingectomy: right/left/both (Tick whatever is applicable)**

2. **Meaning:** Female reproductive system consists of uterus, two ovaries and two fallopian tubes. The area adjacent to the uterus on each side where fallopian tube and ovary lie is also called as adnexa. Laparotomy means making an incision on the abdomen. Removal of cyst in the ovary is called as ovarian cystectomy. Removal of ovary is called oophorectomy and removal of fallopian tube is called salpingectomy. In some case the exact origin of the cyst cannot be determined. It can be only said that the cyst is arising from the area adjacent to uterus. They are called as adnexal cysts. In some cases investigations like sonography may be able to further specify the site as "paraovarian" (next to ovary) or "parafimbrial" (next to fimbrial end of the fallopian tube) or "paratubal" (next to fallopian tube). All these cysts are classified as adnexal cysts. Final treatment remains the same; that is surgical removal.

3. **Purpose/ indications: (The list given below only indicates common reasons and does not include all indications):**

I. When the ovarian/ adnexal cysts are large they need to be removed surgically.

II. Cysts with suspicion of malignancy need to be removed.

III. Ovarian cysts caused due to endometriosis.

IV. Cysts causing pain, menstrual irregularities need to be removed.

V. If the chance of cancer of breast or ovary is high then they may be removed as preventive measure.

VI. Swollen and abnormal fallopian tubes

VII. Any other condition: ____ ____ (for manual entry)

4. Description of the procedure: This surgery may be done under regional anaesthesia (where in the lower half of the body is made numb or anaesthetised) or under general anaesthesia (where the patient is put to sleep by giving injection). The doctor makes an incision on the abdomen.The ovary or the cyst is separated from the surrounding structures like bowel, urinary bladder. The blood flow to the area is stopped. Thus the ovarian cyst/ adnexal cyst/ ovary is disconnected and removed from the body. In case if the fallopian tube is to be removed, it is also separated from other structures, blood vessels are tied and is removed.

5. Benefits& effects of the procedure

Ovarian or adnexal cyst is an abnormal growth. Fallopian tubes that are swollen are abnormal too.Thus, removal of the cyst or fallopian tube/s mean removal of the root cause in itself. Removal of the cyst/ fallopian tube/s is expected to relive the symptoms such as pain.

The cyst/ ovary/ ovaries may be sent for further analysis to find out exact nature of the growth so that further treatment may be advised. Effects of removal of the ovaries: As ovary/ ovaries are removed there is no chance that woman will suffer from the disease of ovary in future life. If both ovaries are removed, the secretion of female hormones will cease completely.In some women, removal of both ovaries may lead to symptoms of hormone deficiency such as hot flushes, bone pain, bone weakness, weight gain, hair loss, vaginal dryness. If woman is nearing menopause the hormonal secretion, in any case, may be very low. Thus, removal of ovaries may not cause so much of disturbances. Medicines can be prescribed by the doctor to deal with the symptoms.

<u>Removal of fallopian tube/tubes</u>: When fallopian tubes are swollen or blocked, they will not function normally in any case. Infection, increase in swelling, pus formation may further increase the trouble. Removal of abnormal tubes is expected to relieve the symptoms. When ovary on the particular side is removed,

it is common to remove the fallopian tube from the same side. Thiseliminates the chance of fallopian tube getting diseased in future. There is some scientific evidence that cancer of

ovary originates in the later part of the tube. Thus, removal of fallopian tube may provide protection from possibility of ovarian cancer in future. However more studies are being done to prove this.

6. Alternatives:

- Medical therapy:

For smaller sized cysts, hormonal or non-hormonal medicines can be given.

- Other way to do the surgery

Once it is decided to remove the cyst or ovary or fallopian tube it is important to understand the other way to do the surgery. In laparoscopic surgery there are multiple small incisions made on the abdomen. But all cases may not be suitable for laparoscopy. If the cysts are large in size, laparoscopy may not be suitable.

Abdominal surgery is conventional surgery, doesn't need high tech equipment and is relatively less complex in nature. The doctorgets easy access to the tissues. These are the advantages of open surgery over other modes of surgery.

7. Consequences of refusal of the procedure:

If surgery is not done, one may need to use other modalities of treatment, as discussed above.

If no treatment is done, one may not get relief from the suffering. The cyst may further grow or the disease may further progress.

8. Outline of substantial risks:

With the advances in medical science, surgeries have become safer than in the past. However, any surgery has its own set of risks and complications.

a. Excessive bleeding/ blood accumulation: Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

b. Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

c. Injury to surrounding structures: During the surgery various organs in the abdominal cavity such as urinary bladder, ureter, bowel, major blood vessels may get injured. The injury may or may not get detected immediately. Whenever detected it may need to be repaired by necessary additional surgery.

d. Anesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anaesthesia. Headache after spinal and other regional anaesthesia are not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

e. Every Individual has a different way to cope up. Sometimes the scar becomes thick and some- times it stays as thin line. Some- times hernia formation may occur later. In some cases, surgery leads to adhesions of tissues.Some- times hernia formation may occur later.

f. Very rare-conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery.

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date/time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR LAPROSCOPIC OVARIAN CYSTECTOMY OR OOPHORECTOMY OR SALPINGECTOMY

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

1. Name of the procedure: Laparoscopy for

- **Ovarian/ adnexal cystectomy: Ovarian / adnexal cyst right/ left/ both**
- **Oophorectomy: right / left / both**
- **Salpingectomy: right / left / both (Tick whatever is applicable)**

2. Meaning: Female reproductive system consists of uterus, two ovaries and two fallopian tubes. The area adjacent to the uterus on each side where fallopian tube and ovary lie is also called as adnexa.Laparoscopy means use of telescope to see and operate on the organs inside the abdomen.Removal of cyst in the ovary is called as ovarian cystectomy. Removal of ovary is called oophorectomy and removal of fallopian tube is called salpingectomy. In some case the exact origin of the cyst cannot be determined. It can be only said that the cyst is arising from the area adjacent to uterus. They are called as adnexal cysts. In some cases investigations like sonography may be able to further specify the site as "paraovarian" (next to ovary) or "parafimbrial" (next to fimbrial end of the fallopian tube) or "paratubal" (next to fallopian tube). All these cysts are classified as adnexal cysts. Final treatment remains the same; that is surgical removal.

3. Purpose/ indications: (The list given below only indicates common reasons and does not include all indications):

I. When the ovarian/ adnexal cysts are large they need to be removed surgically.
II. Cysts with suspicion of malignancy need to be removed.
III. Ovarian cysts caused due to endometriosis.
IV. Cysts causing pain, menstrual irregularities need to be removed.
V. If the chance of cancer of breast or ovary is high then they may be removed as preventive measure.
VI. Swollen and abnormal fallopian tubes
VII.
VIII. Any other condition: ____ (for manual entry)

4. Description of the procedure: This surgery may be done under regional anaesthesia (where in the lower half of the body is made numb or anaesthetised) or under general anaesthesia (where the patient is put to sleep by giving injection). In Laparoscopy, the doctor makes multiple small incisions on the abdomen. A telescope is put inside the

abdomen. The abdomen is filled up with a gas (carbon dioxide or air). The doctor sees the structures through the telescope. The doctor operates using specialised instruments. Theovary/ fallopian tube/s or the cyst is separated from the surrounding structures like bowel, urinary bladder, blood vessels. The blood flow to the area is stopped. Thus the ovarian cyst/ ovary is disconnected and removed from the body. In case if the fallopian tube is to be removed, it is also separated from other structures, blood vessels are tied and is removed.

5. **Benefits & effects of the procedure:**

Ovarian or adnexal cyst is an abnormal growth. Fallopian tubes that are swollen are abnormal too. Thus, removal of the cyst or fallopian tube/s mean removal of the root cause in itself. Removal of the cyst/ fallopian tube/s is expected to relive the symptoms such as pain.

The cyst/ ovary/ ovaries may be sent for further analysis to find out exact nature of the growth so that further treatment may be advised.

Effects of removal of the ovaries: As ovary/ ovaries are removed there is no chance that woman will suffer from the disease of ovary in future life. If both ovaries are removed, the secretion of female hormones will cease completely..In some women, removal of both ovaries may lead to symptoms of hormone deficiency such as hot flushes, bone pain, bone weakness, weight gain, hair loss, vaginal dryness. If woman is nearing menopause the hormonal secretion, in any case, may be very low. Thus, removal of ovaries may not cause so much of disturbances. Medicines can be prescribed by the doctor to deal with the symptoms.

Removal of fallopian tube/tubes: When fallopian tubes are swollen or blocked, they will not function normally in any case. Infection, increase in swelling, pus formation may further increase the trouble. Removal of abnormal tubes is expected to relieve the symptoms. When ovary on the particular side is removed, it is common to remove the fallopian tube from the same side. This eliminates the chance of fallopian tube getting diseased in future. There is some scientific evidence that cancer of ovary originates in

the later part of the tube. Thus, removal of fallopian tube may provide protection from possibility of ovarian cancer in future. However more studies are being done to prove this.

6. **Alternatives:**

- **Medical therapy:**

For smaller sized cysts, hormonal or non-hormonal medicines can be given.

- **Other way to do the surgery**

Once it is decided to remove the cyst or ovary or fallopian tube it is important to understand the other way to do the surgery.

The same surgery may be done by open surgery technique as well. However, in this case, the doctor will make larger incision. Thus, laparoscopy is more cosmetic than open surgery. These are the advantages of laparoscopy overother modes of surgery.

7. **Consequences of refusal of the procedure:**

If surgery is not done, one may need to use other modalities of treatment, as discussed above.

If no treatment is done, one may not get relief from the suffering. The cyst may further grow or the disease may further progress.

8. **Outline of substantial risks:**

With the advances in medical science, surgeries have become safer than in the past. However, any surgery has its own set of risks and complications.

a. Excessive bleeding/ blood accumulation: Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

b. Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and

sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

c. Injury to surrounding structures: During the surgery various organs in the abdominal cavity such as urinary bladder, ureter, bowel, major blood vessels may get injured. The injury may or may not get detected immediately. Whenever detected it may need to be repaired by necessary additional surgery.

d. Anaesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anaesthesia. Headache after spinal and other regional anaesthesia are not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

e. Every Individual has a different way to cope up. Sometimes the scar becomes thick and some- times it stays as thin line. Some- times hernia formation may occur later. In some cases, surgery leads to adhesions of bowel. In later life, if the supports around the vagina get loosened, the vagina may prolapse partly or fully.

f. Very rare-conditions:Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery.

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Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR INTRAUTERINE CONTRACEPTIVE DEVICE

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the surgery

1. **Name of the procedure: Insertion of an intrauterine contraceptive device**
2. **Meaning:** Insertion of the contraceptive device into the uterus through vagina.
3. **Purpose/ indications:** Woman may choose this method of contraception after understanding benefits and risks of this method. This is a temporary method of contraception. Once inside the uterus it may provide contraceptive effect for 3 to 10 years depending on the type of the device used.

4 **Description of the procedure:** This procedure can be done in doctor's clinic also. Some women may desire to take a sedative for the procedure. Drugs to soften the mouth of the uterus may be advised to be taken few hours prior to the procedure. The woman is requested to lie on examination table with legs apart. An instrument is gently inserted into the vagina to see the mouth of the uterus or cervix. The intrauterine contraceptive device (IUCD) is inserted through the cervix into the uterus. IUCD has a string at the bottom that hangs down through the cervix in the vagina. The doctor will trim this string. Woman may self-examine by inserting finger in the vagina. The same string is pulled to remove the IUCD later. The partner while having intercourse will not be able to fell or get hurt by the IUCD as it is sitting in the uterus and not vagina.

5 **Benefits & effects of the procedure:**

Benefits:

- It is a temporary method for spacing and the contraceptive effect can be reversed immediately on removal
- Does not need any action to be taken during intercourse to ensure contraception (like condoms)
- Does not need motivation on daily basis as is required for oral pills ingestion.
- Hormone containing IUD have added advantage of controlling abnormal uterine bleedings due to various causes.

6 Alternatives if any:

- For spacing other alternatives are barrier methods (Condoms), oral contraceptive pills, progesterone monthly injection or if available implants
- Various types of IUCD are available. They differ in their expiry period efficacy and effect on menstrual blood flow:

7 Consequences of refusal of the procedure:

There is a risk of unwanted pregnancy if contraceptive is not used.

8 Outline of substantial risks:

Side effects are rare, and mild. Some of the side effects are as under:

- Cramps: Mild cramping for few days may be expected.
- Fainting: Some women feel dizzy during or after the procedure.
- Irregular or Heavy Periods: Some women may experience irregular and/or heavy menstrual periods. If the problem persists, doctor may advice to change the copper device and insert hormonal IUCDs. This may make periods lighter and shorter. Sometimes they may stop menstruation altogether.
- Pregnancy: The chance of failure of this method is very low -- about 1%. But if it does happen, the chance of miscarriage and early delivery is higher. Some have reported potentially increased chance of abnormalities in the foetus due to exposure of copper. Woman should be cautious if she desires to continue the pregnancy.
- Ectopic Pregnancy: This is when a fertilized egg implants outside the uterus. The pregnancy can't survive, and continuation could be dangerous to life because rupture of ectopic pregnancy can cause internal bleeding. Each year, only 1 out of 1,000 women with an IUCD present with ectopic pregnancy
- Infection: An IUCD slightly raises the chance of infection of the uterus, fallopian tubes, or ovary.
- Perforation: Rarely, the IUCD pokes through the wall of the uterus. Surgical removal may be needed
- Expulsion: This is when the IUCD falls out of the uterus. It happens in about 3% of women.

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date / time)

Signature of the patient: ....

> **instruction To Patient:** Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

Part II: Undertaking

I, Miss/Mrs..., aged .... years, female residing at ……………………………………………………………………give my free and valid consent for myself/my ....

Miss/Mrs...aged .... years residing at ....

....

I am aware that the procedure will be will be carried out under the directions of ....

I am aware that anaesthesia may be administered under the instructions of Dr..

I state that

I. I have been explained about my medical condition.

II. I have been given the information about

the procedure as mentioned above in column 1-8 and I am aware of

a. the nature of procedure,

b. its purpose, benefits and effect,

c. alternatives if any available,

d. an outline of substantial risks

e. and adverse consequences of refusing treatment

III. I have been counselled about nature of anaesthesia, benefits, purpose, effects and alternatives and substantial risks

IV. I consent to observing, photographing, recording or televising of the surgery for medical, scientific or educational purpose provided my identity is not revealed by the picture or descriptive text accompanying them

V. I accept that medical science is not perfect and has its limitations. No guarantees can be given about result or outcome.

VI. I agree to cooperate fully with my doctor and to follow instructions and recommendations about my care and treatment.

VII. I confirm that I have given all the details to the doctor about myself, including past medical history including previous ailments, surgeries and allergies to any drugs

VIII. Apart from the above-mentioned general information, I have been specifically informed about individual risks related to ....

....

....

....

(to be mentioned by doctor about any specific problems related to that patient)

IX. I was encouraged to ask any question related to this operation and had been answered well all the questions asked, way in which we could understood.

X. It was also explained that expected outcome in this treatment /procedure /operation is good/Fair/Poor

XI. I understand that I have a right to change/withdraw the consent and will inform the doctor in time (if needed)

By signing below, I indicate that I have understood the above information in language I understand

I am giving my free consent willingly with sound mind, without any undue influence, coercion, fraud, misrepresentation or mistake of facts.

I request Dr...to perform upon me the above-mentioned procedure.

....(interpreter)has read out above mentioned to me and explained everything to me in the .... language (in case of patient giving thumb impression or not understanding language of consent printed) (This should be in vernacular language)

Sign	Sign / Thumb impression
Dr.'s Name .... Reg.no: .... Date: .... Time: .... AM / PM	Patient Name: .... Age .... years: .... Date: .... Time: .... AM / PM
Sign Name of witness .... Age .... years: .... Address .... Date: .... Time: .... AM / PM	Sign Name of witness .... Age .... years: .... Relationship with patient .... Address .... Date: .... Time: .... AM / PM

CONSENT FOR NATURAL CHILDBIRTH , VACCUM AND FORCEPS

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the procedure

1. Name of the procedure:

Vaginal delivery/ birth: When the baby and the placenta are delivered through birth canal (vagina), it is called as "vaginal delivery/ birth." The vaginal birth may have following aspects:

Natural/ Normal delivery: The process of vaginal birth starts naturally and ends into the child birth. No medicines or procedures are required. If during the process, the perineum is torn, it is sutured by the healthcare worker.

In some cases, the health worker may need to intervene, use medications or do some procedures such as:

- Augmentation of labour
- Episiotomy.
- Instrumental delivery: Forceps / Ventouse
- Repair of perineal tear

It may not be possible to predict beforehand, whether intervention will be needed or no.

2. Meaning:

The pregnant woman's uterus starts contracting giving rise to discomfort and pain. She may experience bleeding and/ or passage of water from vagina. The health worker examines (vaginal examination is usually done) the woman, confirms that the process of birth has begun and admits her in the hospital. Her condition and the baby's condition are monitored on regular basis. The mouth of the uterus slowly opens up to 10 centimeters. As this happens, the baby starts coming down. With the pushing efforts of the woman, the baby comes out of the birth canal. After some time, the placenta separates and comes out.

The process of birth / delivery usually begins naturally. It progresses into the birth of the baby and does not need any medical intervention such as use of medicines, injections or any procedures. Such vaginal birth is called as natural or normal delivery/ childbirth.

If during the process, the perineum (area around the vaginal opening) is injured, it is repaired by taking sutures.

Following medical interventions may be needed in addition:

- Augmentation: When the labor process slows down too much, the health worker uses medicines to hasten the process. Some of the medicines increase the frequency and intensity of the uterine contractions and others facilitate the dilation of cervix. This may be done by giving injections, using injections through drips or using tablets and gels. This is called augmentation of labor.
- Episiotomy; To facilitate the delivery of the baby, the health worker may need to widen the opening of vagina by giving a cut. This is called as episiotomy.
- Instrumental delivery: In order to facilitate the delivery, the health worker may need to use instruments like vacuum (ventouse) and/or forceps to deliver the head.
- During the deliver the perineum may tear. It may need repair by suturing. Sometimes the cervix and the vagina may develop injuries. These may need repair by suturing.

  Emergency situations occurring during the vaginal delivery may warrant additional procedures such as:
- Emergency cesarean section:

  This may be needed in following situations:
  - When baby in the womb is not doing well and is distressed,
  - When labor is not progressing
  - If the baby is not descending down in spite of all efforts
  - If the mother's condition gets worsened suddenly.
  - MRP (Manual Removal of Placenta): As stated earlier, the placenta gets detached and falls out on its own after the child birth. If this does not happen, even after giving medicines, it needs to be removed by a surgical procedure.

- Check curettage: If the pieces of placenta and membranes are stuck inside the uterus or if there is excess bleeding after delivery, this surgical procedure is needed.
- Labor analgesia and epidural analgesia: If woman cannot bear the pain of contractions, she may opt for labor analgesia. This may include use of medicines. These medicines can be given by various ways. In Epidural labor analgesia, a thin catheter is inserted in the back with the help of injection. Medicines are given through the catheter to reduce the pain of labor.

If any of the above-mentioned additional procedure is needed, a separate consent form needs to be signed by the woman.

3. Purpose/ indications: (The list given below only indicates common reasons and does not include all indications):

As stated earlier, the process of childbirth is usually a natural phenomenon. But in some cases, additional medical interventions are needed.

- Augmentation: When the labour process slows down too much, the health worker uses medicines to hasten the process. Some of the medicines increase the frequency and intensity of the uterine contractions and others facilitate the dilation of cervix. This may be done by using injections, using injections through drips or using tablets and gels. This is called augmentation of labour
- Episiotomy; To facilitate the delivery of the baby, the attending health worker may need to widen the opening of vagina by giving a cut. This is called episiotomy.
- Instrumental vaginal delivery: Once the mouth of the uterus opens up fully, the mother's efforts are enough to get the baby out. Sometimes this gets unduly prolonged. Need for instrumental delivery using vacuum (ventouse) or forceps may arise in following conditions:
  - If baby is showing signs of distress or if mother is getting too exhausted or the last part of delivery (second stage) gets too prolonged.
  - If there are medical conditions that warrant shortening on the last part of delivery process.

The research has shown that both, vacuum(ventouse) as well as forceps are safe and the doctor is the best person to decide which is more suitable for delivery in given case.

4. Description of the procedure:

The pregnant woman's uterus starts contracting giving rise to discomfort and pain. She may experience bleeding and/ or passage of water from vagina. The health worker examines (vaginal examination is usually done) the woman, confirms that the process of birth has begun and admits her in the hospital. If the process of labour has not begun, the woman may be sent home. The mouth of the uterus slowly opens up to 10 centimeters. As this happens, the baby starts coming down. With the pushing efforts of the woman, the baby comes out of the birth canal. After some time, the placenta separates and comes out.

During the process of labour, woman's condition and the baby's condition is monitored on regular intervals. The woman should follow the advice of the health worker about diet and mobility. Sometimes, she may be advised to avoid food or liquids for few hours.

Pain management: If the woman cannot bear the pain, health care worker helps her to choose appropriate option to reduce the pain.

5. Benefits & effects of the procedure:

Vaginal delivery, especially natural child birth is beneficial compared to caesarean for the obvious reason that it is a natural process of child birth and does not involve surgery. Mother becomes ambulatory soon. However, no one can ensure or assure that no medical interventions will be needed during the process of childbirth.

The possibility of adherent and/or low-lying placenta in future pregnancies is less after vaginal birth as against caesarean section.

6. Alternatives:

The only alternative to vaginal birth is caesarean section surgery

7. Consequences of refusal of the procedure:

After the uterine contractions get initiated, the birth is inevitable.

The safety of this natural process of child birth increases when it is monitored by the health worker. Hence vaginal birth in hospital is encouraged.

Since it is a natural process mothers' willingness to co-operate is vital for safe outcome.

Refusal of episiotomy may lead to ragged tears of the perineum. Such tears may lead to excessive bleeding and at times may extend to and damage the muscles and vessels of the pelvic floor, sphincter muscles of the anal opening or even lower part of the rectum. Damage to the anal sphincter can lead to fecal and flatus incontinence.

Refusal of instrumental delivery, may cause delay in the delivery. This may lead to neonatal complications and maternal complications.

8. Outline of substantial risks:

Even though it is a natural process, there are possibilities of risk and complications to mother and baby during or after delivery. It may warrant active management with drugs or emergency surgeries. It may lead to prolonged hospital stay.

- Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.
- At times after the delivery of the baby, the placenta does not separate and come out as expected. It may require manual removal under anesthesia.
- Sudden Obstetric deaths during or after delivery is very rare but not unknown. The causes of such occurrence are amniotic fluid embolism, pulmonary embolism, associated life-threatening medical conditions of the mother, severe bleeding due to APH, PPH.

- Specific risks related to instrumental delivery are as follows:

  Ventouse may causes a small swelling on the scalp (Chignon) which settles down in few days. Bleeding inside the head of the baby is very rare. Injury to the bony skull of the baby is rare but not unknown.
- Every Individual has a different way to cope up. Sometimes the scar becomes thick and some- times it stays as a thin line. Unhealed episiotomy at times may gape and need active management with drugs, local medications and at time re-suturing. Improper healing may cause tract formation between vagina and other organs.
- If microorganisms from outside enter the body (via surgical cuts or birth canal) and are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the birth canal. Additional doses of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.
- Excessive bleeding during labour (Before delivery is called as Antepartum hemorrhage [APH], after delivery is called as post-partum hemorrhage [PPH]) are complications which may occur without any warning and may at times become life threatening. They require active management with drugs, blood and blood products and at times surgical intervention under anesthesia in the operation theatre. Surgical intervention such as immediate delivery by cesarean, cleaning of the womb(evacuation), devascularization of the womb and rarely even removal of the womb (hysterectomy).
- Unexpected events causing morbidity in natural/normal delivery are
  - Cerebral palsy in the fetus: The research has proved that cerebral palsy most commonly occurs due to some event during pregnancy.

- Shoulder dystocia: Sometimes after the delivery of the head, the shoulder gets stuck in the birth canal and requires several maneuvers to complete the delivery. This may cause injuries to the baby and at times even severe morbidity and mortality. These events are unpredictable.
- Other birth injuries to the bony parts and nerves of the baby are rare but not unknown.

- Anesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anesthesia. Headache after spinal and other regional anesthesia is not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.
- Very rare conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery. Rarely if the uterus is densely stuck to other organs the doctor may find it difficult to complete the procedure.

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date/time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

Part II: Undertaking

I...aged..................years, residing at

....

State that I/ my ....(relation) Ms. .... age residing at am/is being admitted for VAGINAL DELIVERY/ CHILD BIRTH

I am aware that the procedure will be carried out under the directions of .... (name of the doctor) and the team of doctors, nurses, assistants).

I state that:

I. I have been explained about the nature of the procedure.

II. I have been given the information about the procedure (mentioned in clause 1 -8) and I am aware of the following:

   a. nature and procedure
   b. its purpose, benefits and effect;
   c. alternatives if any available;
   d. an outline of the substantial risks
   e. adverse consequences of refusing treatment

III. I understand that during the course of the procedure, the doctor may find other unanticipated, unhealthy conditions that may need specific actions / procedures/ surgery. If doctor feels that it will be beneficial to treat such condition at the same time and if I am not in the mental/physical capacity to give consent, the doctor may take necessary decision after discussing with Mr/Mrs...(relation). I authorise the above mentioned person to give proxy consent on my behalf.

IV. In order to save the life, it may even be necessary to do additional surgeries or procedures which are beyond the scope of the consent given by me. I authorise the doctor to take such decisions if the need be.

V. I have been counselled about the nature of anaesthesia, benefits, purpose, effects and alternatives and substantial risks.

VI. I give consent for blood /blood products transfusion. I have been explained about the benefits, purpose, effects, alternatives and substantial risks associated with it.

VII. I consent to observing, photographing or televising of the surgery for medical, scientific, or educational purpose, provided my identity is not revealed by the picture or by descriptive text accompanying them.

VIII. I accept that medical science is not perfect and has certain limitations. No guaranty has been given about result or outcome.

IX. I agree to co-operate fully with my doctor and to follow instructions and recommendations about my care and overall treatment.

X. I confirm that I have given accurate and relevant details about myself including past medical history, previous ailments, surgeries and allergies to the doctor.

XI. Apart from the above-mentioned general information, I have been specifically informed about individual risks related to

....

.... (to be written physically by the doctor. This refers to specific problems pertaining to that patient).

XIII. I was encouraged to ask questions related to disease and the procedure/operation. All the questions/queries were answered to my satisfaction.

By signing below, I indicate that I have understood the above information (point 1 -8 & I to XII) in the language that I understand.

I am giving my free consent willingly with sound mind, without any undue influence, coercion, fraud, misrepresentation or mistake of facts.

....

....

....

(space for hand written declaration by the patient or relative in his or her language)

Sign	Sign / Thumb impression
Dr.'s Name ...... Reg.no: ...... Date: ...... Time: ...... AM / PM	Patient Name: ...... Age ...... years: ...... Date: ...... Time: ...... AM / PM
Sign Name of witness ...... Age ...... years: ...... Address .... Date: ...... Time: ...... AM / PM	Sign Name of witness ...... Age ...... years: ...... Relationship with patient ...... Address .... Date: ...... Time: ...... AM / PM

Revalidation:
I revalidate my consent for additional procedure for instrumental delivery. I reiterate that I have understood the need, purpose, benefits and effect; alternatives, substantial risks, adverse consequences of refusing treatment.

Signature of the patient / relative (if the patient cannot sign)

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR CESAREAN SECTION

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the surgery

1. **Name of the procedure:** Caesarean Section. The most common type of the cesarean section is Lower Segment Caesarean Section (LSCS)

2. **Meaning:**

Baby delivers through the birth canal or vagina during natural child birth. When baby (and placenta) are delivered by making an incision on the abdomen, it is called as Cesarean section. In this, the doctor makes a cut on the abdomen and the uterus to deliver the baby. The cut on the uterus may be made on the upper part or the lower part. In almost all cases, the cut is made on the lower part of the uterus. This is called as lower segment cesarean section (LSCS). If agreed beforehand, additional surgeries such as female sterilization (also called tubal ligation), removal of ovarian cyst & removal of fibroids etc. may be done.

3. **Purpose/ indications: (Not all but only common indications are listed below.)**

Cesarean is indicated when vaginal birth is not possible or risky to the mother / baby or both. Here are few common examples:

- Immediate delivery is needed: The baby in the womb (fetus) is in distress and needs immediate delivery. If the fetus cannot cope with the stress of labour, the fetal heart sound pattern may become abnormal. Thus, immediate delivery is needed.
- Inadequate space or improper position:

  If the space in the birth canal is inadequate for the baby to descend or baby is in transverse or breech (buttocks/ legs down position), or there is obstruction due to tumors, or attempts of vaginal delivery have failed.

- Uterus prone to rupture: Previous surgeries on the uterus making it prone for rupture (giving way) in response to uterine contractions of labour (e.g., Previous LSCS, previous Myomectomy or Hysterotomy). Previous surgeries on the genital tract making vaginal delivery difficult or not possible (vaginal repairs).
- Risk of life-threatening bleeding in vaginal delivery: When the placenta is low and if the

  labour begins, it can lead to life threatening bleeding. Thus, cesarean is preferred.
- Medical conditions in the mother making it risky to wait for and go through labour pains and vaginal delivery. (e.g., pregnancy induced hypertension, gestational diabetes, heart disease etc.)
- Cesarean on demand: In this the woman demands cesarean as her preferred mode of delivery.
- If vaginal delivery is likely to be more complex. For example, large baby, elderly mother, previous pregnancy losses etc.

4. **Description of the procedure:** When surgery is planned in advance, it is called "Elective Cesarean section." When vaginal delivery is tried but the situation becomes risky to the baby or mother or both, or if the vaginal delivery is not possible, cesarean is planned in emergency. This is called as " Emergency Cesarean section".

Caesarean section may be done under regional anaesthesia (where in the lower half of the body is anaesthetised) or under general anaesthesia where the patient is put to sleep by giving injection. The abdomen is opened layer by layer by making an incision on the abdomen. This incision may be horizontal or vertical. Baby is delivered after making a cut on the uterus. Sometimes instrument like vacuum extractor or forceps may be required to deliver the baby. This is followed by delivery of the placenta and membranes. Uterus and abdominal wall are sutured in systematic manner or layer wise manner.

Additional surgery (e.g., tubal ligation), (removal of fibroids removal of ovariancyst) if already planned is performed before the abdomen is stitched up.

5. Benefits of the procedure:

a) Benefit to the baby (foetus): When foetus is in distress, it needs to be delivered at earliest. C section is a quick way to achieve delivery. If vaginal birth is likely to be traumatic or risky to the baby, C section reduces that risk.

b) Benefit to the mother: Surgery relieves the mother from expected complications of vaginal birth.

6. Alternatives:

The only alternative to Caesarean section is vaginal delivery.

7. Consequences of refusal of the procedure:

If the surgery is not done in time, the woman has no other alternative to go through vaginal birth. with it expected complication

8. Outline of substantial risks:

With the advances in medical science, surgeries have become safer than in the past. However, any surgery has its own set of risks and complications.

Cesarean sections done in emergency and more so done is later part of labour have more likelihood of having complications.

a. Anesthesia: It has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anesthesia. Headache after spinal and other regional anesthesia is not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

b. Excessive bleeding/ blood accumulation: Usually, the uterus contracts after the baby is delivered. Sometimes the uterus does not contract and this may lead to excessive bleeding. This problem may occur after vaginal delivery as well. This is called as Postpartum Hemorrhage (PPH). PPH may occur without any warning and may at times become life threatening. Severe

bleeding can occur from blood vessels within the uterus or around the uterus. Such bleeding is controlled by using medicines, injections, by compression sutures on the uterus, by ligating bleeding vessels, by blocking the blood vessels to the uterus and using blood and blood products. Removal of uterus is rarely required and is done only as a life saving measure.

In cases the blood gets accumulated inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding as a life saving measure may be required.

c. Infection: Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

d. Injury to surrounding structures: While the doctor is making space to deliver the baby from the womb, the surrounding structures such as urinary bladder, ureter, bowel, blood vessels may get injured. The injury may or may not get detected immediately. Whenever detected it may needs to be repaired by necessary additional surgery.

e. Every Individual has a different way to cope up. Sometimes the scar becomes thick and some- times it stays as a thin line. Sometimes incision does not heal well and requires extra care, dressings, medicines and repair. Some- times hernia formation may occur later. In some cases, surgery leads to adhesions of bowel, bladder with the uterus. Occasionally, when the woman gets pregnant next time, the placenta gets abnormally stuck to the lower part of the uterus.

f Very rare conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery. Sudden shock may be caused due to peculiar condition called amniotic fluid embolism. In this case, the fluid around the baby gets mixed with the blood and causes massive reaction. This is a rare, but fatal complication.

g. Neonatal morbidity

I. Commonly, caesarean is done for foetal indications or when the baby in the womb is in trouble. Neonatal morbidity noted after caesarean section is not due to the surgery per se. It is the aftermath of the basic problem or insult. For example, imagine that the fetus (baby) is not able to cope up with the stress of labour and is in distress. The C section is done to relieve the problem. Yet the baby may need resuscitation after birth. Thus, the resuscitation is needed due to the distress and not because of caesarean.

ii. Minor injuries while delivering the baby are not uncommon. They don't pose any major threat to the baby perse.

iii. Baby may have fast breathing after caesarean birth. This settles down on its own and may need observation and some treatment.

iv. Cerebral palsy in the neonate: It is an unfortunate complication following any delivery.

The research has proved that cerebral palsy most commonly occurs due to some event

during pregnancy.

v. Other birth injuries to the bony parts and nerves of the baby are rare but not unknown.

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date/time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

Sign	Sign / Thumb impression
Dr.'s Name .... Reg.no: .... Date: .... Time: .... AM / PM	Patient Name: .... Age .... years: .... Date: .... Time: .... AM / PM
Sign Name of witness .... Age .... years: .... Address .... Date: .... Time: .... AM / PM	Sign Name of witness .... Age .... years: .... Relationship with patient .... Address .... Date: .... Time: .... AM / PM

CONSENT FOR ANAESTHESIA

(Pending opinion by PSA-Pune Society of Anaesthesiologist and ISA-Indian Society of Anaesthesiologists)

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about anaesthesia

1. **Name of the procedure: General anaesthesia / Regional anesthesia (Spinal, Epidural, Block) / Epidural analgesia / Monitored standby care for local anaesthesia with/without sedation/ General Anaesthesia combined with Regional anaesthesia (Tick mark what is applicable/ strike out what is not applicable)**

2. **Meaning:**

- Analgesia: It means use of drugs or gases for giving pain relief to the patient during surgical procedures done under local anaesthesia and /or sedation. This pain relief is not 100% and the patient remain conscious and aware during the procedure
- Anaesthesia: It means use of drugs and gases to make the patient temporarily unconscious and reversibly block the pain perception. It also relaxes the muscles of the body so also make the surgeons work easily
- Regional anaesthesia: Use of drugs to reversibly numb a specific part of the body by blocking the respective nerves. Patient remains conscious during the procedure. When peripheral nerves are blocked it is called peripheral nerve block. When drug is injected in the spinal canal

  (inside the dura layer) it is called spinal anaesthesia. It numbs the lower part of the body. When the drug is injected outside the dura of the spinal cord it is called epidural anaesthesia
- Epidural analgesia: When the drug injected in the epidural canal is enough to cause pain relief without causing 100% numbness it is called epidural analgesia. This is commonly used for pain relief in labour

- Monitored care by anaesthesiologist in cases done under local analgesia with/without sedation: When an anaesthesiologist attends a surgery done under local analgesia with or without sedation to manage any unforeseen reactions and complications to the drugs used.

3. **Purpose/ indications: (The list given below only indicates common reasons and does not include all indications):**

   I. Analgesia is given for pain relief during surgical procedure.

   II. Anaesthesia is for complete but reversible block of pain perception. In general anaesthesia this is also associated with temporary loss of consciousness.

   III. Regional analgesia is for pain relief of specific body part during surgery and also sometimes for post-operative pain relief

   IV. Regional anaesthesia is for complete but reversible block of pain perception in a specific body part

   V. Epidural analgesia is commonly used for labour analgesia

   Any other condition: ____

   ____(for manual entry)

4. **Description of the procedure:**

   - General Anaesthesia: Drugs are given through a vein to put the patient to a deep sleep and cause blockage of pain perception. If required drugs are also given to relax the muscles of the body. A breathing tube is inserted through the wind pipe so as to control the breathing because muscle relaxing drugs also cause relaxation of breathing muscles. After the surgery is over certain drugs are given to reverse the muscle

     relaxation and level of consciousness. Once the patient starts breathing on his/her own the tube is removed. In some situations, the breathing tube may have to be kept in the wind pipe for a prolonged period of time even after the surgery

   - Spinal anaesthesia: Drug is injected in the spinal space after puncturing the dura membrane. This numbs the lower part of the body for an adequate period of time for the surgery to be completed with complete block of pain perception.

- Epidural anaesthesia: A very fine plastic catheter is inserted and placed in the epidural space (just before the spinal space without puncturing the dura). Measured amount of anaesthetic drug is injected at specific time interval to cause complete blockage of pain perception and relaxation of muscles in the lower part of the body. The catheter may be kept for 36-48 hrs for injecting drugs for post-operative pain relief
- Epidural analgesia: The technique is same as in epidural anaesthesia however the drug dose is just enough to cause high degree of pain relief but no numbing of the lower limbs
- Peripheral nerve block: Drugs is injected close to the nerve to black the pain sensation supplied by that nerve during surgery General anaesthesia and regional anaesthesia are combined in certain indicated cases

5. Benefits & effects of the procedure :

a. Benefits and effects of General anesthesia: Compete pain relief, deep sedation and temporary loss of consciousness makes the patient go through the surgery easily without awareness. Muscle relaxation of the whole body makes it convenient for the surgeon to complete the surgery and tackle the pathology properly.

b. Benefits and effects of spinal anesthesia: Complete pain relief occurs without loss of consciousness and awareness. Muscle relaxation of the lower body makes it convenient for the surgeon to complete the surgery and tackle the pathology properly. It is preferred over general anesthesia in cases of respiratory deficiencies, elderly patients and full-term pregnancies

c. Benefits of Epidural anaesthesia technique: Complete pain relief occurs without loss of consciousness and awareness. Muscle relaxation of the lower part of the body makes it convenient for the surgeon to complete the surgery and tackle the pathology properly. It is preferred over general anesthesia in cases of respiratory deficiencies, elderly patients and full-term pregnancies. Advantage over spinal anesthesia technique is that the epidural catheter can be kept in for continued post-operative pain relief for 36-48 hrs.

d. Benefits of peripheral nerve block: It specifically blocks the body part which is being operated upon. It leads to completed pain relief and muscle relaxation of the specific body part without loss of consciousness and awareness. Post-operative pain relief continues for longer period of time and the nausea and vomiting associated with oral and IV drugs is avoided. This technique is commonly used in orthopadic cases. Patients can participate in physiotherapy earlier

e. Functions of vital organs are monitored and maintained by the anesthetist attending the patient

6. Alternatives:

Once the decision of surgery is taken by the patient there is no alternative to getting the surgery done under some kind of anesthesia

Among the types of anaesthesia described patient may prefer one over the other, however it is prudent to discuss the pros ad cons of the different alternatives with the anesthesiologist in order to choose the one which is most preferable given the medical condition of the patient.

7. Consequences of refusal of the procedure:

Once decision of surgery is taken there is no question of refusing anesthesia for the same. Patient may refuse one technique of anaesthesia in preference to another. However it is prudent to discuss the preference of a technique with the anesthesiologist and understand the consequence of refusal of a particular technique in preference to another

8. Outline of substantial risks:

With the advances in medical science, anaesthesia has become safer than in the past. However, any anesthesia technique has its own set of risks and complications.

a. Risk of anaesthesia changes as per the medical condition of the patient. These conditions are graded as per the American Society of Anaesthesiologist. It is called as ASA grading.

i. ASA grade no 1: A normal healthy patient.

ii. ASA grade no 2: Patient with mild systemic disease without substantive functional limitations (eg.well controlled diabetics or hypertensives)

iii. ASA grade no 3 : Patient with severe systemic disease with functional limitations

iv. ASA grade no 4: patient with severe systemic disease that is a constant threat to life (eg. Chronic asthama etc)

v. ASA grade no 5: A moribund patient who is not expected to survive without the operation

vi. ASA grade no 6: A declared brai dead patient whose organs are being removed for donation

vii. Addition of E denotes emergency surgery Emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part.

b. The different techniques have specific risks as mentioned below

i. General anesthesia can lead to temporary hoarseness, soreness of throat, mouth or teeth injury, nausea, vomiting and rarely aspiration and pneumonia.

ii. Regional anaesthesia or analgesia techniques using spinal or epidural technique can cause temporary decrease / loss of feeling and movements of lower part of the body, headache, persistent weakness, residual pain and backache. Dural puncture is a rare complication of epidural technique which leads to headache in post-operative period. It is effectively treated with drugs and sometimes needs a technique called as “blood patch”. Inadequate anesthesia or failure of anaesthesia may warrant use of alternate anesthesia technique

iii. Peripheral nerve block technique can cause temporary decreased or loss of feeling and/or movements of specific limb or area of body, persistent numbness, weakness, residual pain, blood vessel injury or nerve injury. Inadequate anesthesia or failure of anaesthesia may warrant use of alternate anesthesia technique

c. Patient's condition can get complicated secondary to surgical complication

  i. Excessive bleeding can warrant transfusion of blood and blood products and need for drugs and IV fluids to tackle severe hypotension which may at times lead to vital organ failure

  ii. Surgical injury to surrounding structures may need to be tackled by the surgeon and this may lead to prolongation of anesthesia.

  iii. Anesthesia presents additional challenges if the patient is in an infected condition because infection often takes a toll on vital organ

d. Past or existing medical problems may increase the risk of anaesthesia during and after surgery eg: Heart problem (Heart attack, angina, blood pressure, valvular heart disease), Lung problems (Asthma, chronic obstructive pulmonary diseases, infection), other diseases like diabetes, kidney diseases, liver diseases, thyroid, alcoholism, chronic smoking, blood thinning medications etc. Patients are expected to discuss complete medical history, medications, addictions and past anaesthetic complications so that all necessary precautions are taken to avert such complications

e. Very rare conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), arrythmias, shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery and anaesthesia. Emergency situation and high ASA grading causing mortality is a very rare but not an unknown complication.

. THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date/time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

Part II: Undertaking

I...aged.......................years, residing at

....

give my free and valid consent for ....

(name of operation / procedure.)

upon myself / my.. (relation)

(Mr./Mrs...aged..................years, residing at

....

I am aware that the surgery will be carried out under the directions of

.... (name of the doctor) and the team of doctors, nurses, assistants.

I am aware that the anaesthesia will be administered under the instructions of Dr ....(name of the anaesthesiologist)

I am aware that the type of anaesthesia planned for my surgery is ....

I state that:

I. I have been explained about the nature of the disease that I am suffering from.

II. The pre-anesthesia check-up was done by Dr .... on................. I was personally counselled about the anaesthesia and was also given a leaflet that had detailed information about anaesthesia regarding.

a. nature and procedure of the anesthesia technique

b. its purpose, benefits and effects

c. alternatives;

d. an outline of the substantial risks

e. adverse consequences of refusing the anaesthesia technique

I have gone through the details mentioned in clause 1 -8 and have clarified my doubts with the doctor.

III. I understand that during the course of the surgery, the doctor may find other unanticipated, unhealthy conditions that may need specific actions / procedures/ surgery and anaesthesia. If doctor feels that it will be beneficial to treat such condition while performing proposed surgery and if I am not in the mental/physical capacity to give consent, the doctor may take necessary decision after discussing with Mr/Mrs.................................(relation). I authorise the above mentioned person to give proxy consent on my behalf.

IV. In order to save the life it may even be necessary to do additional surgeries or procedures and prolonged anaesthesia which are beyond the scope of the consent given by me. I authorise the doctor to take such decisions if the need be.

V. I give consent for blood /blood products transfusion. I have been explained about the benefits, purpose, effects, alternatives and substantial risks associated with it.

VI. I consent to observing, photographing or televising of the surgery for medical, scientific, or educational purpose, provided my identity is not revealed by picture or by descriptive text accompanying them.

VII. I accept that medical science is not perfect and has certain limitations. No guaranty has been given about result or outcome.

VIII. I agree to co-operate fully with my doctor and to follow instructions and recommendations about my care and overall treatment.

IX. I confirm that I have given accurate and relevant details about myself including past medical history, previous ailments, surgeries and allergies to the doctor.

X. Apart from the above mentioned general information, I have been specifically informed about individual risks related to

....

……………………………………………………………………………….(to be written physically by the anesthesiologist. This refers to specific problems pertaining to that patient).

XI. I was encouraged to ask questions related to disease and the procedure/operation and anaesthesia. All the questions/queries were answered to my satisfaction.

By signing below I indicate that I have understood the above information (point 1 -8 & I to XIII)

I in the language that I understand.

I am giving my free consent willingly with sound mind, without any undue influence, coercion, fraud, misrepresentation or mistake of facts.

....

....

....

(space for hand written declaration by the patient or relative in his or her language)

Sign	Sign / Thumb impression
Dr.'s Name .... Reg.no: .... Date: .... Time: .... AM / PM	Patient Name: .... Age .... years: .... Date: .... Time: .... AM / PM
Sign Name of witness .... Age .... years: .... Address .... Date: .... Time: .... AM / PM	Sign Name of witness .... Age .... years: .... Relationship with patient .... Address .... Date: .... Time: .... AM / PM

CONSENT FOR LAPROSCOPIC SURGERY FOR ECTOPIC PREGNANCY

(Pending opinion by PSA-Pune Society of Anaesthesiologist and ISA-Indian Society of Anaesthesiologists)

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

I...aged............ years, female / male

residing at...

....

give my free, and valid consent for admission of myself / my ....(relation)

(Mr./Mrs...aged .... years residing

at..

under the treatment of Dr ....

Part I: Information about the surgery

1. **Name of the procedure: Laparotomy for ectopic pregnancy**

   Following procedures may be done:

   Salpingectomy: Right/ left / both

   Salpingostomy: Right/ left/ both

   Surgical management of non-tubal ectopic

   (Tick mark what is applicable/ strike out what is not applicable)

2. **Meaning:**

   An ectopic pregnancy is one that grows outside the uterus (womb). It occurs in just over 1% of pregnancies. A pregnancy cannot survive in these situations and it can pose a serious risk to the patient.

   In a normal pregnancy, the fertilised egg moves from the fallopian tube into the uterus, where the pregnancy grows and develops. If this does not happen, the fertilised egg may implant and start to develop outside the uterus, leading to an ectopic pregnancy.

   Most ectopic pregnancies develop in the fallopian tubes (tubal ectopic) but rarely they can occur in other places (ovarian, cervical, abdominal, interstitial etc)

An ectopic pregnancy can be life-threatening because as the pregnancy gets bigger it can burst (rupture), causing severe pain and internal bleeding.

Surgical removal of the ectopic pregnancy is the aim of the surgery. When the surgery is performed by using a telescope and other instruments by making small incisions on the abdomen, it is called as laparoscopic ectopic surgery. One of the following procedures are done laparoscopically

- Salpingectomy means surgical removal of the affected tube along with the ectopic pregnancy
- Salpingostomy means removal of ectopic without removal of the tube.

3. Purpose/ indications:

Because an ectopic pregnancy cannot lead to the birth of a baby, aim of management is to end the pregnancy in order to reduce the risks to patient's health.

If the patient presents with signs and symptoms of a ruptured ectopic, the surgery may have to be done as an emergency lifesaving surgery.

The option chosen depends on several factors such as weeks of pregnancy, clinical condition, level of beta hCG, scan report, future pregnancy plans, fertility status, presence of emergency life threatening situation, facilities available in the healthcare set-up and the personal views and preferences of the patient

4. Description of the procedure: This surgery may be done under regional anaesthesia (where in the lower half of the body is made numb or anaesthetised) or under general anaesthesia (where the patient is put to sleep by giving injection).

The doctor makes multiple small incisions on the abdomen. Gas (carbon dioxide or air) is filled with a specialised gadget in the abdomen. Blood is sucked out and using specialised energy devices, the ectopic is excised and the material is removed from the abdomen.

To have the best chance of a future pregnancy inside the uterus, and to reduce the risk of having another ectopic pregnancy, patient will usually be advised to have the affected fallopian tube removed (this is known as a salpingectomy)

If the patient has only one fallopian tube or the other tube does not look healthy, the chances of getting pregnant are already affected. In this circumstance, the patient may be advised to have a different operation (known as a salpingotomy) that aims to remove the pregnancy without removing the tube. It carries a higher risk of a future ectopic pregnancy but it also means that the patient is still able to have a pregnancy in the uterus in the future.

Surgical treatment of non-tubal ectopic depends on the site of ectopic, level of beta hCG, USG report and clinical condition.

5. **Benefits & effects of the procedure :**

An ectopic pregnancy cannot result in birth of baby and if unattended it can sometimes lead to life threatening situation because of rupture leading to internal bleeding. Excision of the ectopic pregnancy prevents such a catastrophe.

Effects of removal of the tube: If the patient has a normal looking other side tube, the possibility of pregnancy in future exists. However, the incidence of another ectopic in future becomes higher. If other tube is absent or diseased and salpingectomy had to be done because salpingostomy was surgically not feasible, in future the patient may have to resort to artificial reproductive techniques like IVF for pregnancy.

There is some scientific evidence that cancer of ovary originates in the later part of the tube. Thus, removal of fallopian tube may provide protection from possibility of ovarian cancer in future. However more studies are being done to prove this.

6. **Alternatives:**

- **Expectant management:**

Ectopic pregnancies sometimes dissolve and disappear on their own – similar to a miscarriage. Depending on the situation, it may be possible to monitor the hCG levels with blood tests every few days until these are back to normal. Although patient may not

have to stay in hospital, a strict vigil is needed on the symptoms and patient is advised to visit the hospital as soon as these symptoms appear, so that the life-threatening situation arising due to rupture of the ectopic is tackled.

Expectant management is not an option for all women. It is usually only possible when the pregnancy is still in the early stages and when the patient has only a few or no symptoms. Success rates with expectant management are highly variable and range from 30% to 100%. This mainly depends on pregnancy hormone levels; higher serum hCG levels is associated with a lower chance of success.

- **Medical management:**

In certain circumstances, an ectopic pregnancy may be treated by medication (drugs). The fallopian tube is not removed. A drug (methotrexate) is given as an injection. This prevents the ectopic pregnancy from growing and the ectopic pregnancy gradually disappears. Most women only need one injection of methotrexate for treatment. However, 15 in 100 women (15%) need to have a second injection of methotrexate.

If the pregnancy is beyond the very early stages or the hCG level is high, methotrexate is less likely to succeed.

Seven in 100 women (7%) will need surgery even after medical treatment.

Many women experience some pain in the first few days after taking the methotrexate, but this usually settles with paracetamol or similar pain relief. Although it is known that long-term treatment with methotrexate for other illnesses can cause significant side effects, this is rarely the case with one or two injections as used to treat ectopic pregnancy.

Treatment of ectopic pregnancy with methotrexate is not known to affect the capacity of the ovaries to produce eggs in the future.

The patient is advised to wait for 3 months after the injection before planning another pregnancy

- **Other modes of ectopic surgery:**

Once it is decided to remove the ectopic, it is important to understand the ways to do the surgery. The surgery can be done by making a surgical cut on the abdomen or by using laparoscopy.

Laparoscopic surgery involves multiple but small incisions and hence is more cosmetic in nature. Recovery of the patient is faster than in open surgery.

7. **Consequences of refusal of the procedure:**

If surgery is not done, woman may need to choose other alternative modalities as discussed above. There can be a risk to life if the ectopic ruptures and there is internal bleeding.

8. **Outline of substantial risks:**

With the advances in medical science, surgeries have become safer than in the past. However any surgery has its own set of risks and complications.

a. Excessive bleeding / blood accumulation : Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

b. Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

c. Injury to surrounding structures: While ectopic tissue is being separated the surrounding structures such as urinary bladder, ureter, bowel, blood vessels may get injured. The injury may or may not get detected immediately. Use of electricity and heat may cause injury to surrounding structures which may become evident later. Whenever detected it needs to be repaired by necessary additional surgery.

d. Whenever detected it needs to be repaired by necessary additional surgery.

e. Anesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anesthesia. Headache after spinal and other regional anesthesia is not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

f. Every Individual has a different way to cope up. Sometimes the scar becomes thick and some- times it stays as a thin line. Some- times hernia formation may occur later. In some cases surgery leads to adhesions of bowel. .

g. Very rare conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke
or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery.

. THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date/time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR LAPROTOMY SURGERY FOR ECTOPIC PREGNANCY

(Pending opinion by PSA-Pune Society of Anaesthesiologist and ISA-Indian Society of Anaesthesiologists)

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

1. Name of the procedure: Laparotomy for ectopic pregnancy

Following procedures may be done:

Salpingectomy: Right/ left / both

Salpingostomy: Right/ left/ both

Surgical management of non-tubal ectopic

(Tick mark what is applicable/ strike out what is not applicable)

2. Meaning:

An ectopic pregnancy is one that grows outside the uterus (womb). It occurs in just over 1% of pregnancies. A pregnancy cannot survive in these situations and it can pose a serious risk to the patient.

In a normal pregnancy, the fertilised egg moves from the fallopian tube into the uterus, where the pregnancy grows and develops. If this does not happen, the fertilised egg may implant and start to develop outside the uterus, leading to an ectopic pregnancy.

Most ectopic pregnancies develop in the fallopian tubes (tubal ectopic) but rarely they can occur in other places (ovarian, cervical, abdominal, interstitial etc)

An ectopic pregnancy can be life-threatening because as the pregnancy gets bigger it can burst (rupture), causing severe pain and internal bleeding.

Surgical removal of the ectopic pregnancy is the aim of the surgery. Abdomen is opened (laparotomy) and ectopic is removed in one of the following ways.

- Salpingectomy means surgical removal of the affected tube along with the ectopic pregnancy
- Salpingostomy means removal of ectopic without removal of the tube.

3. Purpose/ indications:

Because an ectopic pregnancy cannot lead to the birth of a baby, aim of management is to end the pregnancy in order to reduce the risks to patient's health.

If the patient presents with signs and symptoms of a ruptured ectopic, the surgery may have to be done as an emergency lifesaving surgery.

The option chosen depends on several factors such as weeks of pregnancy, clinical condition, level of beta hCG, scan report, future pregnancy plans, fertility status, presence of emergency life threatening situation, facilities available in the healthcare set-up and the personal views and preferences of the patient

4 Description of the procedure: This surgery may be done under regional anaesthesia (where in the lower half of the body is made numb or anaesthetised) or under general anaesthesia (where the patient is put to sleep by giving injection). The doctor makes an incision on the abdomen. The blood in the abdominal cavity (in case of ruptured ectopic) is sucked out and the ectopic pregnancy is surgically excised.

To have the best chance of a future pregnancy inside the uterus, and to reduce the risk of having another ectopic pregnancy, patient will usually be advised to have the affected fallopian tube removed (this is known as a salpingectomy)

If the patient has only one fallopian tube or the other tube does not look healthy, the chances of getting pregnant are already affected. In this circumstance, the patient may be advised to have a different operation (known as a salpingotomy) that aims to remove the pregnancy without removing the tube. It carries a higher risk of a future ectopic pregnancy but it also means that the patient is still able to have a pregnancy in the uterus in the future.

Surgical treatment of non-tubal ectopic depends on the site of ectopic, level of beta hCG, USG report and clinical condition.

5. Benefits & effects of the procedure :

An ectopic pregnancy cannot result in birth of baby and if unattended it can sometimes lead to life threatening situation because of rupture leading to internal bleeding. Excision of the ectopic pregnancy prevents such a catastrophe.

Effects of removal of the tube: If the patient has a normal looking other side tube, the possibility of pregnancy in future exists. However, the incidence of another ectopic in future becomes higher. If other tube is absent or diseased and salpingectomy had to be done because salpingostomy was surgically not feasible, in future the patient may have to resort to artificial reproductive techniques like IVF for pregnancy.

There is some scientific evidence that cancer of ovary originates in the later part of the tube. Thus, removal of fallopian tube may provide protection from possibility of ovarian cancer in future. However more studies are being done to prove this.

6. Alternatives:

- **Expectant management:**

Ectopic pregnancies sometimes dissolve and disappear on their own – similar to a miscarriage. Depending on the situation, it may be possible to monitor the hCG levels with blood tests every few days until these are back to normal. Although patient may not have to stay in hospital, a strict vigil is needed on the symptoms and patient is advised to visit the hospital as soon as these symptoms appear, so that the life-threatening situation arising due to rupture of the ectopic is tackled.

Expectant management is not an option for all women. It is usually only possible when the pregnancy is still in the early stages and when the patient has only a few or no symptoms. Success rates with expectant management are highly variable and range from 30% to 100%. This mainly depends on pregnancy hormone levels; higher serum hCG levels is associated with a lower chance of success.

- **Medical management:**

In certain circumstances, an ectopic pregnancy may be treated by medication (drugs). The fallopian tube is not removed. A drug (methotrexate) is given as an injection. This prevents the ectopic pregnancy from growing and the ectopic pregnancy gradually disappears. Most women only need one injection of methotrexate for treatment. However, 15 in 100 women (15%) need to have a second injection of methotrexate.

If the pregnancy is beyond the very early stages or the hCG level is high, methotrexate is less likely to succeed. Seven in 100 women (7%) will need surgery even after medical treatment.

Many women experience some pain in the first few days after taking the methotrexate, but this usually settles with paracetamol or similar pain relief. Although it is known that long-term treatment with methotrexate for other illnesses can cause significant side effects, this is rarely the case with one or two injections as used to treat ectopic pregnancy.

Treatment of ectopic pregnancy with methotrexate is not known to affect the capacity of the ovaries to produce eggs in the future.

The patient is advised to wait for 3 months after the injection before planning another pregnancy

- **Other modes of ectopic surgery:**

Once it is decided to remove the ectopic, it is important to understand the ways to do the surgery. The surgery can be done by making a surgical cut on the abdomen or by using laparoscopy.

Abdominal surgery is conventional surgery, doesn't need high tech equipment and is relatively less complex in nature. The surgeon gets relatively easy access to the tissues.

7. **Consequences of refusal of the procedure:**

   If surgery is not done, woman may need to choose other alternative modalities as discussed above.

   There can be a risk to life if the ectopic ruptures and there is internal bleeding.

8. **Outline of substantial risks:**

   With the advances in medical science, surgeries have become safer than in the past. However any surgery has its own set of risks and complications.

a. Excessive bleeding/ blood accumulation: Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

b. Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

c. Injury to surrounding structures: While ectopic tissue is being separated the surrounding structures such as urinary bladder, ureter, bowel, blood vessels may get injured. The injury may or may not get detected immediately. Whenever detected it need to be repaired by necessary additional surgery.

d. Anesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anesthesia. Headache after spinal and other regional anesthesia is not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

e. Every Individual has a different way to cope up. Sometimes the scar becomes thick and some- times it stays as a thin line. Some- times hernia formation may occur later. In some cases surgery leads to adhesions of bowel. .

f. Very rare conditions: Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery.

. THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date/time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR LAPROSCOPIC SURGERY FOR DIAGNOSIS & OR TREATMENT OF ENDOMETRIOSIS / ENDOMETRIOTIC CYST

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the surgery

1. **Name of the procedure: Laparoscopy for endometriosis / endometriotic chocolate cyst or cysts including**
   - **Diagnosis and dissection of tissues,**
   - **Ablation of endometriotic patches, removal of endometriotic cysts from affected ovary (cystectomy)**
   - **Removal of affected ovary/ ovaries**
   - **Removal of ovary/ies (Oophorectomy) along with fallopian tube/s (salpingectomy) (tick whatever is applicable)**
   - ....

     (for manual entry)
2. **Meaning:** Female reproductive system consists of uterus, two ovaries and two fallopian tubes. The area adjacent to the uterus on each side where fallopian tube and ovary lie is also called as adnexa. Laparoscopy means use of telescope to see and operate on the organs inside the abdomen. Endometriosis is a disease in which the lining of the uterus (called endometrium) starts developing at other places. It is common to see endometriosis developing on the ovaries, surface of the uterus and other pelvic organs. Some times it forms cysts which are filled with chocolate colored fluid. Some times it can develop in the muscle of the uterus making the uterus swollen. This is called as adenomyosis. Though less common, it can also involve intestines, urinary bladder & bowel. . This abnormal tissue causes significant irritation to the tissues leading to inflammation. Tissues stick to each other and cause malfunction of the organs. Those women who suffer from endometriosis may have painful and/ or heavy or irregular menstruation, painful intercourse, bleeding in urine and stools during menstrual periods.

They may not get pregnant because of this problem. Some times women have no symptoms and cysts are picked up on routine checkup or sonography. Milder variety of endometriosis without any cyst formation may get diagnosed only after the laparoscope is introduced. Removal of cyst in the ovary is called as ovarian cystectomy. Removal of ovary is called oophorectomy and removal of fallopian tube is called salpingectomy. In some case the exact origin of the cyst cannot be determined during investigations. This may happen because of the distorted anatomy caused by the disease itself. It can only be said that the cyst is arising from the area adjacent to uterus. They are called as adnexal cysts. In some cases investigations like sonography may be able to further specify the site as "paraovarian" (next to ovary) or "parafimbrial" (next to fimbrial end of the fallopian tube) or "paratubal" (next to fallopian tube). All these cysts are classified as adnexal cysts. Final treatment remains the same; that is surgical removal.

3. **Purpose/ indications: (The list given below only indicates common reasons and does not include all indications):**

   I. Women is not able to conceive or wants to get pregnant some time later in life.

   II. When the ovarian/ adnexal cysts are large they need to be removed surgically.

   III. When woman is suffering from symptoms of endometriosis are described above.

   IV. Cysts with suspicion of malignancy need to be removed.

   V. When endometriosis is strongly suspected the surgery is done to confirm the diagnosis and treat it.

   VI. Any other condition: ....
   ....(for manual entry)

4. **Description of the procedure:** This surgery may be done under regional anaesthesia (where in the lower half of the body is made numb oranaesthetised) or under general anaesthesia (where the patient is put to sleep by giving injection). In Laparoscopy, the doctor makes multiple small incisions on the abdomen.

A telescope is put inside the abdomen. The abdomen is filled up with a gas (carbon dioxide or air). The doctor sees the structures through the telescope. The doctor operates using specialised instruments. The ovary/ fallopian tube/s or the cyst is separated from the surrounding structures like bowel, urinary bladder, blood vessels. The blood flow to the area is stopped. Thus the ovarian cyst/ ovary is disconnected and removed from the body. In case if the fallopian tube is to be removed, it is also separated from other structures, and is removed. Endomtriotic tissue is destroyed using heat enrgey created by specialised gadgets. As mentioned above, endometriosis causes distortion of anatomical structures and poses a challenge to the doctor.

5. **Benefits& effects of the procedure:**

The surgery is aimed to remove/ destroy as much abnormal tissue as possible maintaining normal functioning of the organs. During the surgery the doctor gets a chance to grade the severity of the disease. This is important especially if the woman is planning to get pregnant. Endomtetriosis is a disease that has high chance of recurrence after any treatment including surgery. So even after the surgery, additional treatment, usually in the form of medicines, is needed. When endometriosis involves ovaries, it may reduce the ovarian reserve. Thus surgical treatment at least temporarily halts the deterioration of the ovarian function (which may already be affected by the disease).

Effects of removal of the ovaries: If ovary is fully converted into the chocolate cyst and there is no normal tissue left, removal of cyst may amount to removal of ovary. In some women, removal of both ovaries may lead to symptoms of hormone deficiency such as hot flushes, bone pain, bone weakness, weight gain, hair loss, vaginal dryness. If woman is nearing menopause the hormonal secretion, in any case, may be very low. Thus, removal of ovaries may not cause so much of disturbances. Medicines can be prescribed by the doctor to deal with the symptoms. Thus removal of ovary is done if woman is elderly or if disease is extremely severe

Removal of fallopian tube/tubes: When fallopian tubes are swollen or blocked, they will not function normally in any case. Again removal of fallopian tubes is done only when the tubes are diseased , disease is severe or woman is elderly. There is some scientific evidence that cancer of ovary originates in the later part of the tube. Thus, removal of fallopian tube may provide protection from possibility of ovarian cancer in future. However more studies are being done to prove this.

6. **Alternatives:**

- **Medical therapy:**

  Various medicines can be given to temporarily stop the growth of endometriosis. Hormonal tablets, injections or intra uterine system are available. These medicines may keep pain at bay. Usually menstruation stops or gets infrequent..

- **Other way to do the surgery**

  Removal of uterus and both ovaries can significantly reduce the abnormal tissue as well as growth of new endometriotic tissue. Of course, this option will only be suitable for those who are not interested in child bearing and menstrual function.

7. **Consequences of refusal of the procedure:**

If surgery is not done, one may need to use other modalities of treatment, as discussed above. If no treatment is done, one may not get relief from the suffering. The cyst may further grow or the disease may further progress.

8. **Outline of substantial risks:**

With the advances in medical science, surgeries have become safer than in the past. However, any surgery has its own set of risks and complications.

a. Excessive bleeding/ blood accumulation: Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

b. Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery.

Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

c. Injury to surrounding structures: While the telescope is being put inside and /or while tissues are being separated other surrounding structures such as urinary bladder, ureter, bowel, blood vessels may get injured. During the surgery various organs in the abdominal cavity such as urinary bladder, ureter, bowel, major blood vessels may get injured. As discussed above altered anatomy caused due to endometriosis may make it difficult for the doctor to dissect and separate the tissues from one another. The injury may or may not get detected immediately. Whenever detected it may need to be repaired by necessary additional surgery.

d. Anaesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anaesthesia. Headache after spinal and other regional anaesthesia are not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

e. Every Individual has a different way to cope up. Sometimes the scar becomes thick and some- times it stays as thin line. Some- times hernia formation may occur later. In some cases, surgery leads to adhesions of bowel. In some cases, endometriosis spreads to the site of incision as well.

f. Endometriosis is known to reoccur after some time. Hence long term treatment is required even after the surgery.

g. If the doctor finds that the tissues are badly stuck and cannot be separated, the doctor may have to abandon the procedure halfway or only do bear minimum clearance of endometriosis Or may resort to open surgery.

h. Very rare-conditions:Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs,

formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery.

vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery.

THIS INFORMATION LEAFLET WAS RECEIVED ON ....(date /time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR LAPROSCOPIC MYOMECTOMY

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the surgery

1. **Name of the procedure:Laparoscopic Myomectomy**

2. **Meaning:** Fibroids or myomas are common tumors that develop in the uterus.Surgical removal of the myoma/ myomas is called myomectomy. When the surgery is performed by using a telescope or laparoscope it is called as laparoscopic myomectomy. Most often fibroids donot cause any symptoms and are harmless. Hence very small fibroids need not be removed.Most of the fibroids are not cancerous too. Some times fibroids can cause heavy, excessive, irregular bleeding and severe pain during menstruation. They can cause difficulty in getting pregnant. Rarely fibroids can get cancerous. Large fibroids can cause pressure symptoms on surrounding organs.

3. **Purpose/ indications: (The list given below only indicates common reasons and does not include all indications):**

Following fibroids need to be operated upon:

- Fibroids which cause symptoms
- Fibroids which are large
- When there is a suspicion of cancer

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4. **Description of the procedure:** This surgery may be done under regional anaesthesia (where in the lower half of the body is made numb or anaesthetised) or under general anaesthesia (where the patient is put to sleep by giving injection). The doctor makes multiple small incisionson the abdomen.Gas (carbon dioxide or air) is filled with a specialised gadget in the abdomen. The laparoscope is introduced inside the abdominal cavity.The fibroid/ fibroids are identified. The uterus is cut open to reach the fibroid. It is separated from the tissue of the uterus. The blood vessels feeding the fibroid are cauterised by use of special energy devices or ligated. The fibroid is separated.

The cut on the uterus is stitched back.Same procedure is done for other fibroids. A special instrument called morcellator is used to cut the fibroids into smaller pieces which can then be retrieved through small incisions made on the abdomen. Finally the incisions on the abdomen is closed by taking stitches. Sometimes, doctor may need view the uterus from inside using hystroscope

5. Benefits& effects of the procedure :

The fibroids are responsible directly for the medical condition and the suffering. Thus, removal of the fibroids means removal of the root cause in itself.

After removal of fibroids, the uterus is expected to continue its biological function of menstruation and child baring. woman can resume all other activities including sexual intercourse after recovering from the surgery.

It must be noted that nearly thirty percent women may find another fibroid (newly formed) in later life.. Special precautions are needed to be taken during pregnancy and child birth after removal of fibroid surgery. There is a risk that that area of uterus from where fibroid was removed may remain weak and rupture during the process of labour. Hence, doctor may prefer to do caesarean section to avoid this risk.

6. Alternatives:

- **Medical therapy:**

If woman is suffering from excessive and / or irregular bleeding, hormonal or non-hormonal medicines can be given to her. There can be oral medicines or injections. Hormones can be delivered by a device fitted in the uterus.These medical treatments have their own side effects and failure rates.

- **Other surgical procedures:**

Instead of removal of fibroids,entire uterus can be removed. It is obvious that woman will not menstruate or get pregnant after the uterus is removed. Usually, this method is preferred by those who are elderly and not interested in having children any more.

- **Other modes of myomectomy:**

Once it is decided to remove the fibroids, it is important to understand the ways to do the surgery. The surgery can be done by making a surgical cut on the abdomen or through the

birth passage or vagina(A telescope called hysteroscope may be used)or by using laparoscopy. Abdominal surgery is conventional surgery, doesn't need high tech equipment and is relatively less complex in nature. But the doctor has to make sufficient incision on the abdomen to retrieve the tumour.

Vaginal surgery for fibroids is only reserved for specific conditions. If the fibroids are inside the cavity of the uterus or coming out through the uterus, only then this surgery is possible.

7. Consequences of refusal of the procedure:

If surgery is not done, woman may need to choose other alternative modalities as discussed above. If no treatment is done, woman may not get any relief from the suffering.

8. Outline of substantial risks:

With the advances in medical science, surgeries have become safer than in the past. However any surgery has its own set of risks and complications.

a. Excessive bleeding/ blood accumulation: Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

b. Infection: If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

c. Injury to surrounding structures: While the telescope is being put inside and /or while fibroid is being separated from the uterus, other surrounding structures such as urinary bladder, ureter, bowel, blood vessels may get injured. The injury may or may not get detected immediately. Whenever detected it may need to be repaired by necessary additional surgery.

d. Anesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anesthesia. Headache after spinal and other regional anesthesiais not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

e. Every Individual has a different way to cope up. Sometimes the scar becomes thick and some- times it stays as a thin line. Some- times hernia formation may occur later. In some cases surgery leads to adhesions of bowel.As described earlier in the document, the scar on the uterus may give away during labour(very rarely during pregnancy). This may pose a serious danger to the woman and the child.

f. Some times the investigations done before surgery indicate that woman is suffering from fibroid. But the doctor may find that the tumour is not a fibroid. Two common tumours that mimic fibroid are adenomyoma and fibrosarcoma. Fibrosarcoma is a cancerous tumour. This diagnosis is made only when the tissue is checked under microscope. In that case, additional surgery/treatment may be needed. Adenomyoma is a condition of the uterus in which complete removal of the tumour is not possible. The doctor may resect as much part of tumour as possible or take biopsy. Rarely, while doing the surgery the doctor finds that the tumour is not arising from the uterus but arising from ovary or other pelvic organs. The doctor may resort to open surgery if there is any difficulty encountered during laparoscopic surgery.

g. As described above, fibroid is cut into small pieces and removed out through small incisions made on the abdomen. During this process very small pieces may get spread into the abdominal cavity. If the fibroid , by any chance , has cancerous tissue then the same may also spread across the abdomen. Various techniques such as “in bag morcellation”, have been developed to reduce such occurrence.

h. Very rare conditions:Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of

function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery.Rarely if the uterus is densely stuck to other organs the doctor may find it difficult to complete the procedure.

.THIS INFORMATION LEAFLET WAS RECEIVED ON .... (date/time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

CONSENT FOR ABDOMINAL MYOMECTOMY

(Please read the information below carefully. Do ask questions/ queries/ doubts before you sign the document. Please ensure that your relative signs as a witness. Federation of Obstetrical & Gynaecological Society of India wishes you speedy recovery)

Part I: Information about the surgery

1. **Name of the procedure:open/ abdominal Myomectomy**

2. **Meaning:** Fibroids or myomas are common tumors that develop in the uterus.Surgical removal of the myoma/ myomas is called myomectomy. When the surgery is performed by making an incision on the abdomen, it is called as open or abdominal myomectomy.Most often fibroids do not cause any symptoms and are harmless. Hence very small fibroids need not be removed..Most of the fibroids are not cancerous too. Some times fibroids can cause heavy, excessive, irregular bleeding and severe pain during menstruation. They can cause difficulty in getting pregnant. Rarely fibroids can get cancerous. Large fibroids can cause pressure symptoms on surrounding organs.

3. **Purpose/ indications: (The list given below only indicates common reasons and does not include all indications):**

Following fibroids need to be operated upon:

- Fibroids which cause symptoms
- Fibroids which are large
- When there is a suspicion of cancer

4. **Description of the procedure:** This surgery may be done under regional anaesthesia (where in the lower half of the body is made numb or anaesthetised) or under general anaesthesia (where the patient is put to sleep by giving injection). The doctor makes an incision on the abdomen. The fibroid/ fibroids are identified. The uterus is cut open to reach the fibroid. It is separated from the tissue of the uterus. The blood vessels feeding the fibroid are ligated. The fibroid is separated and removed. The cut on the uterus is stitched back. Same procedure is done for other fibroids. After all fibroids are removed, the incision on the abdomen is closed by taking stitches.

5. Benefits& effects of the procedure :

The fibroids are responsible directly for the medical condition and the suffering. Thus, removal of the fibroids means removal of the root cause in itself. After removal of fibroids, the uterus is expected to continue its biological function of menstruation and child baring. woman can resume all other activities including sexual intercourse after recovering from the surgery.

It must be noted that nearly thirty percent women may find another fibroid (newly formed) in later life.. Special precautions are needed to be taken during pregnancy and child birth after removal of fibroid surgery. There is a risk that that area of uterus from where fibroid was removed may remain weak and rupture during the process of labour. Hence, doctor may prefer to do caesarean section to avoid this risk.

6.. Alternatives:

- **Medical therapy:**

  If woman is suffering from excessive and / or irregular bleeding, hormonal or non-hormonal medicines can be given to her. There can be oral medicines or injections. Hormones can be delivered by a device fitted in the uterus. These medical treatments have their own side effects and failure rates.

- **Other surgical procedures:**

  Instead of removal of fibroids, entire uterus can be removed. It is obvious that woman will not menstruate or get pregnant after the uterus is removed. Usually, this method is preferred by those who are elderly and not interested in having children any more.

- **Other modes of myomectomy:**

  Once it is decided to remove the fibroids, it is important to understand the ways to do the surgery. The surgery can be done by making a surgical cut on the abdomen or through the birth passage or vagina(hysteroscopy may or may not be used)or by using laparoscopy.

In laparoscopic surgery there are multiple small incisions made on the abdomen. But all cases may not be suitable for laparoscopy. Especially if fibroids are very large or peculiarly placed or if there have been previous surgeries on the abdomen, laparoscopic surgery may be difficult.

Abdominal surgery is conventional surgery, doesn't need high tech equipment and is relatively less complex in nature. The surgeon gets relatively easy access to the tissues. The cut edges can be approximated better. These are the advantages of open surgery over other modes of surgery.

Vaginal surgery for fibroids is only reserved for specific conditions. If the fibroids are inside the cavity of the uterus or coming out through the uterus, only then this surgery is possible.

7. Consequences of refusal of the procedure:

If surgery is not done, woman may need to choose other alternative modalities as discussed above. If no treatment is done, woman may not get any relief from the suffering.

8. Outline of substantial risks:

With the advances in medical science, surgeries have become safer than in the past. However any surgery has its own set of risks and complications.

a. <u>Excessive bleeding/ blood accumulation:</u> Sometimes excessive bleeding may occur during or after the surgery. Transfusion of blood and blood products may be needed. In case the blood accumulates inside the body cavity, additional procedure or surgery to remove the accumulated blood and stop the bleeding may be required.

b. <u>Infection:</u> If the Pathological microorganisms are not resisted by the body's resistance mechanism, the infection can set in. Infection commonly causes fever, pus formation in the area of the surgery. Additional does of antibiotics and sometimes additional procedure may be required to remove the infection from the body. If the wound does not heal well, it may need repeated dressings or repair again. Severe infection or sepsis is uncommon.

c. Injury to surrounding structures: While fibroids are being separated from the uterus other surrounding structures such as urinary bladder, ureter,bowel, blood vessels may get injured. The injury may or may not get detected immediately. Whenever detected it may need to be repaired by necessary additional surgery.

d. Anesthesia has become much safer in today's world. It is common to have drowsiness, vomiting, weakness, throat pain for a day or two after anesthesia. Headache after spinal and other regional anesthesiais not uncommon. Rarely temporary weakness, numbness in lower part of the body may be caused after regional anesthesia.

e. Every Individual has a different way to cope up. Sometimes the scar becomes thick and some- times it stays as a thin line. Some- times hernia formation may occur later. In some cases surgery leads to adhesions of bowel.As described earlier in the document, the scar on the uterus may give away during labour(very rarely during pregnancy). This may pose a serious danger to the woman and the child.

f. Some times the investigations done before surgery indicate that woman is suffering from fibroid. But the doctor may find that the tumour is not a fibroid. Two common tumours that may mimic fibroid are adenomyoma and fibrosarcoma. Fibrosarcoma is a cancerous tumour. This diagnosis is made only when the tissue is checked under microscope. In that case, additional surgery/ treatment may be needed. Adenomyoma is a condition of the uterus in which complete removal of the tumour is not possible. The doctor may resect as much part of tumour as possible or take biopsy. Rarely, while doing the surgery the doctor finds that the tumour is not arising from the uterus but arising from ovary or other pelvic organs.

g. Very rare conditions : Allergic reaction to any drug including anaesthesia medicines, blood transfusion, need for assistance for respiration (oxygen/ ventilation), shock, stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolus further leading to damage to vital organs, loss of function of any limb or organ or paresis are extremely rare but not unknown complications of any surgery. Rarely if the uterus is dens

.THIS INFORMATION LEAFLET WAS RECEIVED ON ....

(date / time)

Signature of the patient: ....

instruction To Patient: Please Bring This Paper When You Come To The Hospital For Getting The Surgery/ Procedure Done)

PART II : UNDERTAKING

I ....aged.........................years, residing at

....

give my free and valid consent for

....

(name of operation and /or medication /investigation / therapy/procedure etc.)

upon myself/my.. (relation)

(Mr./Mrs..aged..........years, residing at

....

I am aware that the surgery will be carried out under the directions of

.... (name of the doctor) and the team of doctors, nurses, assistants.

I am aware that the anaesthesia will be administered under the instructions of Dr

....(name of the anaesthesiologist)

I state that:

I. I have been explained about the nature of the disease that I am suffering from.

II. I have been given the information about the surgery by doctor. On .... I was also given a leaflet that had detailed information regarding:

   a. nature and procedure of the surgery/ procedure
   b. its purpose, benefits and effect;
   c. alternatives if any available;
   d. an outline of the substantial risks
   e. adverse consequences of refusing treatment

I have gone through the details mentioned in clause 1-8 and have clarified my doubts with the doctor.

III. I understand that during the course of the surgery, the doctor may find other unanticipated, unhealthy conditions that may need specific actions / procedures/ surgery. If doctor feels that it will be beneficial to treat such condition while performing proposed surgery and if I am not in the mental/physical capacity to give consent, the doctor may take necessary decision after discussing with Mr/Mrs..................................(relation). I authorise the above mentioned person to give proxy consent on my behalf.

IV. In order to save the life it may even be necessary to do additional surgeries or procedures which are beyond the scope of the consent given by me. I authorise the doctor to take such decisions if the need be.

V. I have been counselled about the nature of anaesthesia, benefits, purpose, effects and alternatives and substantial risks.

VI. I understand that tissue, secretions, discharges, organs removed during surgery may be sent for appropriate examination for further evaluation or dispose of as deemed fit by the doctor.

VII. I give consent for blood /blood products transfusion. I have been explained about the benefits, purpose, effects, alternatives and substantial risks associated with it.

VIII. I consent to observing, photographing or televising of the surgery for medical, scientific, or educational purpose, provided my identity is not revealed by picture or by descriptive text accompanying them.

IX. I accept that medical science is not perfect and has certain limitations. No guaranty has been given about result or outcome.

X. I agree to co-operate fully with my doctor and to follow instructions and recommendations about my care and overall treatment.

XI. I confirm that I have given accurate and relevant details about myself including past medical history, previous ailments, surgeries and allergies to the doctor.

XII. Apart from the above mentioned general information, I have been specifically informed about individual risks related to

....

....(to be written physically by the doctor. This refers to specific problems pertaining to that patient).

XIII. I was encouraged to ask questions related to disease and the procedure/operation. All the questions/queries were answered to my satisfaction.

By signing below I indicate that I have understood the above information (point 1 -8 & I to XIII) in the language that I understand.

I am giving my free consent willingly with sound mind, without any undue influence, coercion, fraud, misrepresentation or mistake of facts.

....

....

....

(space for hand written declaration by the patient or relative in his or her language)

Sign	Sign / Thumb impression
Dr.'s Name .... Reg.no: .... Date: .... Time: .... AM / PM	Patient Name: .... Age .... years: .... Date: .... Time: .... AM / PM
Sign Name of witness .... Age .... years: .... Address .... Date: .... Time: .... AM / PM	Sign Name of witness .... Age .... years: .... Relationship with patient .... Address .... Date: .... Time: .... AM / PM

FORM C

(See rule 9)

I____ daughter / wife of

______________________________aged about __________years at present residing at ____

(state the permanent address) do hereby give my consent

to termination of my pregnancy at _____________________________________

(state the name' of place where pregnancy is to be terminated)

Place ____________________

Date ____________________

____

Signature / Thumb impression

(to be filled in by guardian where the woman is mentally ill person or minor)

I ____son / daughter / wife of

_____________________________aged about________years at present residing at

Permanent address)__________________________do hereby give my consent to

the termination of the pregnancy of my ward____________________who is a minor

/ mentally ill person at ____

place of termination of pregnancy)

?lace1nature / Thumb impression

Place ____________________

Date ____________________

____

Signature / Thumb impression

Annexure 4

(Standard for Female and Male Sterlization Services)

Informed Consent Form for Sterilization Operation/Re-sterilization

1. **Name of client : Shri / Smt**..
2. **Name of spouse: Shri / Smt** ....
   Address ....
3. **Name of father: Shri** ....
   Address ....
4. **Religion** ....
5. **Educational Qualifications** ....
6. **Business / Occupation** ....
7. **Operating Centre** ....

I, Smt / Shri..., hereby give consent for my sterilization operation. I am married and my husband/wife is alive. My age is ....years and my husband's/ wife's age is..years. We have..............................male and..............................female living children. The age of my youngest living child is.......................................years.

I am aware that I have the option of deciding against the sterilization procedure at any time without sacrificing my rights to other reproductive health services.

a) I have decided to undergo the sterilization/re-sterilization operation on my own without any outside pressure, inducement or force. I declare that I/my spouse has not been sterilized previously (may not be applicable in case of re-sterilization).

b) I am aware that other methods of contraception are available to me. I know that for all practical purposes this operation is permanent. I also know that there are still he above information has been read out and explained to me in my own language, it has been explained to me that this form has the authority of a legal document.some

chances of failure of the operation for which the operating doctor and the health facility will not be held responsible by me .or by my relatives or by any other, person whomsoever.

c) I am aware that I am undergoing an operation that carries an element of risk.

d) The eligibility criteria for the operation have been explained to mc, and I affirm that I am eligible to undergo the operation according to the criteria.

e) I agree to undergo the operation under any type of anaesthesia that the doctor/ health facility thinks suitable for me and to be given other medicines as considered appropriate by the doctor/health facility concerned.

f) If, after the sterilization operation, 1/my spouse experience (s) a missed menstrual cycle, then I/my spouse shall report within two weeks of the missed menstrual cycle to the doctor/health facility and may avail of the facility to get an MTP done free of cost.

g) In case of 'complications following the sterilization operation, including failure, I will accept the compensation as per the existing provisions of the Government of India Family Planning Insurance Scheme as full and final settlement.

h) If I/my wife get (s) pregnant after the failure of the sterilization operation and if I am not able to get the foetus aborted within two weeks, then I will not be entitled to claim any compensation over and above the compensation offered under the Family Planning Insurance Scheme from any court of law in this regard or any other compensation for the upbringing of the child.

I agree to come for follow-up visits to the hospital/institution/doctor/health facility as instructed, failing which I shall be responsible for the consequences, if any

I understand that vasectomy does not result in immediate sterilization. *I agree to come for semen analysis three months after the operation to confirm the success of the sterilization surgery (azoospermia), failing which I shall be responsible for the consequences, if any.

(*Applicable in cases of male sterilization)

I have read the above information.

 # The above information has been read out and explained to me in my own language, it has been explained to me that this form has the authority of a legal document.

Name and signature/thumb impression of the acceptor

....

Signature of witness:

Full name ....

Full address ....

(Only for those beneficiaries who cannot read and write)

Applicable in cases where the client cannot read and where the above information has been read out.

Shri/Smt...has been fully informed about the contents of the Informed Consent Form in his/her own/local language

Signature of counsellor**

Full name ....

Full address ....

I certify that I have satisfied myself that:

1) Shri/ Smt...is within the eligible age group and is medically fit for the sterilization operation.
2) I have explained all clauses to the client and also explained that this form has the authority of a legal document.

3) I have filled out the medical record-cum-checklist and followed the standards for sterilization procedures as laid down by the Government of India.

....	....
Signature of operating doctor	Signature of medical officer in-charge of the facility
Name and address) Seal	(Name and address) Seal

Denial of Sterilization

[certify that Shri/Smt .... is not a suitable client for re-sterilization/sterilization for the following reasons:

1

2

He/she has been advised the following alternative methods of contraception:

1

2

Signature of the counsellor** or
doctor making the decision
(Name and full address)

The counsellor can be any health personnel, including a doctor).