Manual on
Informed Consent
For
Gynaecologic & Obstetric Surgical Procedures

Association of Fellow Gynaecologist, Mumbai
Manual on Informed consent
For Gynaecologic & Obstetric Surgical Procedures

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REV1.1 - YEAR 2014.
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Significance of Informed consent

It is important to understand the concept of “informed consent” and the “legal theories” upon which the law is based. The model consent forms must be sufficiently generic to be acceptable in most of jurisdictions. The readers are cautioned to thoroughly investigate their respective state laws that pertain to informed consent or consult with legal counsel or adviser before attempting to implement the forms or draft policies and procedures dealing with consent issues.

Informed consent is a legal doctrine that requires physician to obtain consent for treatment (diagnostic / therapeutic or medical / surgical, and invasive / noninvasive).

Without informed consent the doctor can be held liable for violating patient’s rights regardless of whether the treatment was appropriate and rendered within the standard of care. The failure to obtain informed consent may result in the physician being accord to battery under common law. It is primary charge in approximately 2% cases of malpractice suits according to 2003 ACOG survey but it is secondary issue in nearly one third cases.

Informed consent is a continuous ongoing process that include exchange of information and development of choices therefore is not mere signing of a consent sheet but involve four basic components which are “voluntariness”, “competence”, “information” and “understanding”. It is recommended that consent issues be addressed on the basis of the substance of the communication and the quality of the evidence.

Patient’s autonomy and patient’s moral right to self-body integrity and self-determination are to be respected but beneficence is also important ethical principle in informed consent. While physicians treating patients always keep in mind about “limited medical resources” available to community.

Healthcare professionals must merge the concepts of “communication and evidence” of consent so that when a challenge arises about an individual case the consent form itself will create a strong presumption that informed consent was obtained.

Informed consent is based on concept of freedom, which means “ability to choose and ability to refuse” treatment therefore recognition of different values, preferences, and alternative treatment options are also basic element of consent sheet.

There are some “practical limitations” such as time limitation, technical limitation, language barriers, communication ability of individual physician, patient’s right, confidentiality some time create problems while making ethical decision.

There are “certain concerns” such as physician’s financial interest, hospital treatment protocols, medical care plans, good practice guidelines while taking informed consent.

According to courts there are “three different degree of disclosure” in informed consent which is following:

- Reasonable physician standard
- Reasonable patient viewpoint standard
- Subjective patient viewpoint (individual ‘s personal need and particular requirement) this is rarely held by court

Procedure of informed consent is suspended in following emergency situations:
(Implied Consent Rule Enables Provider to Act in an Emergency)

- Unconscious patient
- Life threatening conditions
Patient has right to refuse treatment: in such situation, the physician is supposed to document the reason given by the patient for refusal of the proposed treatment and also document possible adverse consequences to future health and wellbeing by refusal, and obtain signature of patient for refusal of treatment or procedure.

Informed consent is better to be obtained in office setting because time for adequate consideration and adequate discussion is provided, where presence of family member can also witness the discussion and sign the consent form as witness. The pamphlets or information leaflet, audiovisual, interactive visuals, greatly assist this whole process of taking informed consent because people usually retain 30% of verbal communication.

**Informed consent usually covers six areas which are following:**

1. **Diagnosis**
2. **Nature and purpose of procedure**
3. **Risk of procedure (general and specific)**
4. **Likelihood of success of procedure**
5. **Reasonable alternative options**
6. **Consequence if procedure is refused and prognosis**

**Consent forms usually include words like:**

- “request for surgery”
- “general risk for surgery”
- “specific risk of surgery”
- “may include but not limited to such complications”
- “reasonable alternatives of treatment such as ……………… “
- “Likelihood of success”

Well informed patients understand better about realistic outcome and medicine is not purely science therefore expectations are reasonable and disclosed complications are not cause of legal actions if it is not due to negligence.

Regulatory agencies statutes may require additional information or more details such as the date, patient’s identity, names of the individuals, who will perform the procedure, specific authorization for anaesthesia, and disposition/disposal of any tissues removed.

“Anaesthesia consent forms” differ from surgical consent forms in that they do not contain the diagnosis, or the surgical or diagnostic procedures. However, in the first paragraph of consent form, the patient acknowledges that the surgical consent process occurred and that he/she understands the reason for anaesthesia. This acknowledgment by the patient is included to protect all parties and assure that appropriate informed consent took place.

**Obtaining Informed Consent from Impaired Patients:**

Among the circumstances that can diminish or impair a patient’s capacity to understand the nature and risk of the proposed treatment, as well as alternatives to it are:

- The inability to speak or understand English
- The patient’s physical condition adversely affects his/her capacity to decide
- Senility or another mental or emotional condition adversely affects the patient’s capacity to comprehend
- Medication, alcohol or drugs prevent comprehension
- The patient must also have reached legal majority (which usually is 18 years old)

**The following are commonly accepted substitutes:**

- A parent (usually only one is necessary) for a minor child
- A husband or wife for a spouse
• A guardian for a ward
• Any adult standing in loco parentis (in place of the parent) for a minor; example, the principal of a boarding school.

**Professional liability claims are increasing every year may be due to following factors:**
• Fees are charge for services
• Reimbursement of doctor’s fee by various medical care agencies or govt. programs
• Third party payer interventions
• Declining income and increasing overhead cost of hospitals / nursing home
• Longer working hours of doctors
• Sizable malpractice premium for indemnity insurances

**Gynaecologists are sued mostly for following reasons:**
• Failure of diagnosis such as cancer
• Higher qualification and more experienced gynaecologist are more likely to be sued because they are treating high risk patients more often so more adverse outcome possibility
• Medical Care given below the national standard of care (medical malpractice)
• Direct cause and effect relationship (poor outcomes) (maloccurrence)

To minimize the risk of law suits, the approach to practice of medicine must have element of risk management which are following:
• Reduce the human errors
• Increase likelihood of desired results
• Documentation and providing medical record
• Investigate incident and adverse outcome in your setting
• Carryout targeted audit
• Having policies and protocols

At individual level following remedial measures to be advised:
• Adopt good surgical technique
• Appropriate knowledge of current developments & therapies
• Adequate documentation of events & procedure
• Good patient communication at offsetting & at indoor care
• Informed consent must for all procedure

This manual about informed consent contains some samples of informed consent sheet of commonest Gynaecologic and Obstetric surgical procedures, Refusal of Treatment form, and consent form for Autopsy of Stillbirth which may be helpful to readers but may be further customized according to individual need.

REFERENCES:
5. www.anaa.com assessed on 27-02-2014
Section – II  Consent form for Gynaecologic Surgery Procedures
Section – II  

Consent form for Gynaecologic Surgery Procedures

Generic Informed Consent for surgery

Family name: .................................................Given name(s): .................................................................
Address: .......................................................... Date of birth/Age: ..................Sex: M / F

Condition and procedure:
This condition requires the following procedure. *(Doctor to document in patient’s own words)*

The following will be performed *(Nature & purpose of procedure)*:

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
- Infection can occur, requiring antibiotics and further treatment.
- Allergic reaction can occur from medicines or by blood transfusion.
- Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
- Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
- Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
- Heart attack or stroke could occur due to the strain on the heart.
- Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
- Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
- Cardiac arrest & Death as a result of this procedure is possible.

Specific Risks:
There are some risks/ complications, which may happened specifically with this type of surgery. They include but are not limited to the following: *(Doctor to Document)*

Significant risks and procedure options: ..........................................................

Risks of not having this procedure: ..........................................................

Anaesthetic: ..........................................................................................

The likelihood of success of above procedure is: Good /fair / poor

Patient consent:
I request Dr. ............................................... to perform upon me the above mentioned procedure.
I acknowledge that the doctor has explained;
- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/ treatment options and their associated risks
- I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
• The procedure may include a blood transfusion.
• Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
• If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
• A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
• I have been given the following Patient Information Sheet/s or explained verbally to me:
  o About Your Anaesthetic
  o About my procedure
  o Blood & Blood Products Transfusion
• I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
• I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
• I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
• I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
• I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: ....................................................... Signature: ......................... Date: .................

Signature of Doctor: ................................................................. Signature of witness: .................................
Section – II  Consent form for Gynaecologic Surgery Procedures

Informed consent for Laparotomy

Family name: ........................................... Given name(s): ..........................................................
Address: ................................................................. Date of birth/Age: ............ Sex: M / F

Condition and procedure:
This condition requires the following procedure. (Doctor to document in patient’s own words)
..........................................................................................................................................................

The following procedure will be performed:
Surgical examination of the inside of the abdomen & the internal organs for any abnormality will be performed. This is done through a 15-30cm cut into the abdomen, depending on the size of the abdomen.

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
• Infection can occur, requiring antibiotics and further treatment.
• Allergic reaction can occur from medicines or by blood transfusion.
• Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
• Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
• Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
• Heart attack or stroke could occur due to the strain on the heart.
• Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
• Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
• Cardiac arrest & Death as a result of this procedure is possible.

Specific Risks:
• Heavy bleeding in the abdomen. This may need fluid replacement, blood transfusion or further surgery. This may mean a longer stay in hospital and longer recovery time.
• Damage to other organs, such as bladder or bowel, which may need further surgery. This may mean a longer stay in hospital and longer recovery time.
• Infections such as pus in the abdomen. This may need surgical drainage and antibiotics.
• Bowel blockage after the operation. This may be temporary or in the longer term. Treatment may be a drip to give fluids into the vein and no food or fluids by mouth. If it doesn’t get better, bowel surgery may be necessary which may include a colostomy. This can be temporary or permanent.
• Adhesions (bands of scar tissue) which can cause bowel obstruction. This can be a short term or long term complication and may need further surgery.
• The wound may not heal normally. The scar can be thickened and red and may be painful. This is permanent and can be disfiguring.
• Poor wound healing. The wound may burst open which may require long term wound care with dressings and antibiotics, or a hernia i.e. rupture can form in the long term. This may need repair by further surgery.
• There is increased risk in smokers of wound and chest infections, heart and lung complications and thrombosis.
• There is very low possibility of a fistula (a connecting passage between one area and another) developing.
• There is a possibility that the symptoms/pain you have been experiencing and the reason for this operation, may not resolve or worsen as a complication of the procedure.
• The cause of pain/other symptoms sometimes cannot be found, if you are having an exploratory operation.

Significant risks and procedure options: ...........................................................................................................
Risks of not having this procedure: ..............................................................................................................
Anaesthetic: ..............................................................................................................................................
The likelihood of success of above procedure is: Good /fair / poor.

Patient consent:
I request Dr. .............................................................. perform upon me above mentioned the procedure.
I acknowledge that the doctor has explained;
• My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
• The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
• Other relevant procedure/ treatment options and their associated risks.
• I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
• My prognosis and the risks of not having the procedure.
• That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
• The procedure may include a blood transfusion.
• Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
• If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
• A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
• I have been given the following Patient Information Sheet/s or explained verbally to me:
  o About Your Anaesthetic
  o Blood & Blood Products Transfusion
  o About Laprotomy
• I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
• I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
• I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
• I accept that medicine is not an exact science and understand that no guarantees can be given to the results & understanding these limitations.
• I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure.

Name of Patient: ...................................................... Signature: ............................................. Date: ............

Signature of Doctor: ................................................................. Signature of witness: ...............................
Section – II  Consent form for Gynaecologic Surgery Procedures

Informed Consent for Hysterectomy
(Vaginal, Laparoscopic, Abdominal)

Family name: ………………………………………………………………
Given name(s): ………………………………………………………………
Address: ……………………………………………………………………
Date of birth/Age: ………… Sex: M /F

Condition and procedure:
The doctor has explained that you have the following condition: (Doctor to document in patient’s own words)

The following procedure will be performed:
Removal of the uterus (womb) will be performed in the following way:

- Vaginal (through the vagina)  Yes /No
- Laparoscopic (‘key hole’)  Yes /No
- Abdominal (through cut in abdomen)  Yes /No
- Ovaries will also be removed  Yes /No
- If yes, which ovaries  Left /Right/Both

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
- Infection can occur, requiring antibiotics and further treatment.
- Allergic reaction can occur from medicines or by blood transfusion.
- Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
- Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
- Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
- Heart attack or stroke could occur due to the strain on the heart.
- Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
- Loss of function of any limb or organ or paralysis/paraplegia/quadruplegia.
- Cardiac arrest & Death as a result of this procedure is possible.

Specific Risks:
- The infection in the operation site or pelvis or urinary tract, requiring antibiotics and further treatment.
- The injury to other organs such as the ureter(s), bladder or bowel.
- A connection (i.e. fistula) may develop between the bladder and the vagina, or bowel or peritoneum.
- The bowel blockage after the operation.

Abdominal Hysterectomy:
- Bleeding into the abdominal wound from surrounding blood vessels.
- Poor wound healing.
- The wound scar may become thickened, red and painful.

Vaginal Hysterectomy:
- Risk of conversion to laparotomy (cut required in the abdomen).
- Higher risk of ureteric injury
- Recurrence of prolapse i.e. Vaginal repair may not be successful in the short or long term and may need further corrective surgery.
- Occurrence of pain during sexual intercourse or altered sexual function after vaginal repair.

Laparoscopic assisted Vaginal Hysterectomy:
- Risk of conversion to laparotomy (incision similar to Abdominal Hysterectomy).
- Change in bladder and bowel habits.
- Feelings of depression and anxiety.
- Onset menopause in pre-menopausal women if both ovaries are removed.

**Significant risks and procedure options:** .................................................................

**Risks of not having this procedure:** .................................................................

**Anaesthetic:** ........................................................................................................

**Patient consent:**
I request Dr. ........................................................................................................ perform upon me the above mentioned procedure.
I acknowledge that the doctor has explained;
- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  - About Your Anaesthetic and/or about Epidural & Spinal Anaesthesia
  - Blood & Blood Products Transfusion
  - About Hysterectomy (Vaginal, Laparoscopic, Abdominal)
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

**On the basis of the above statements, I request to have the procedure**

Name of Patient: ......................................................... Signature: ...................... Date: ...............

Signature of Doctor: ......................................................... Signature of witness: .........................

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REV1.1 - YEAR 2014.
Section – II  Consent form for Gyneacologic Surgery Procedures

Informed consent for Laproscopy

Family name: .................................................................................................................
Given name(s): ..............................................................................................................
Address: ....................................................................................................................... Date of birth/Age: .............. Sex: M /F

Condition and procedure:
The doctor has explained that you have the following condition: (Doctor to document in patient’s own words)
........................................................................................................................................
........................................................................................................................................

The following will be performed:
A trocar will be put into the abdomen and instruments passed down the trocar to examine the inside of the abdomen and pelvis using a camera and video monitor. Sometimes, Adhesions, bands of fibrous tissue, which are most commonly due to previous abdominal or pelvic surgery or infections such as appendicitis or tubal infection grows around the bowel or other organs. If so, the doctor may need to cut these. The doctor may also need to operate on the pelvic organs.

Risks of this procedure
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
• Infection can occur, requiring antibiotics and further treatment.
• Allergic reaction can occur from medicines or by blood transfusion.
• Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
• Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
• Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
• Heart attack or stroke could occur due to the strain on the heart.
• Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
• Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
• Cardiac arrest & Death as a result of this procedure is possible.

Specific risks:
• Adhesions are difficult to diagnose with certainty without surgery and there is no alternative treatment for adhesions other than surgery. Adhesions can be the result of surgery and it cannot, therefore, be guaranteed that they won't come back after surgery to treat them. Sometimes a single band of tissue that is causing the bowel to twist or kink causes the problem. In that case, successful treatment is very high. Other cases, however, are caused by many filmy adhesions and these are much more difficult to get rid of.
• Accidental injury to the bowel, blood vessels and the urinary tract can occur during the passing of the laparoscope. If a complication happens during the surgery, then repair is usually possible at the time - often through the small cuts. However, it may also be necessary to make a larger cut to repair the bowel, blood vessel or urinary tract injuries. In case of bowel injury, it may be necessary for the bowel to be brought out onto the abdomen. This allows waste to drain into a bag worn over the end of the bowel (known as a colostomy) so the injured bowel can heal. This colostomy would normally be closed at a separate operation.
• Heavy bleeding inside the abdomen. His may need fluid replacement, blood transfusion or further surgery. This may mean a longer than expected stay in hospital and longer recovery time.
• Damage to other organs, such as bladder or bowel, which may need further surgery. This may mean a longer than expected stay in hospital and longer recovery time.
• Rarely the gas, which is passed into the abdomen, can cause heart and chest complications.
• Infections such as pus collections in the abdominal cavity. This may need surgical drainage and antibiotics.
• Adhesions (bands of scar tissue) may form and cause a bowel obstruction. This can be a short term or a long term complication and may need further surgery.
• In some people, healing of the wound may be abnormal and the wound can be thickened and red and the scar may be painful.
• A weakness in the wound with the development of a hernia (rupture). This may need further surgery.
• There is increased risk in smokers of wound and chest infections, heart and lung complications and thrombosis.
• There is very low possibility of a fistula (a connecting passage between one area and another) developing.
• There is a possibility that the symptom(s)/pain you have been experiencing and the reason for this operation, may not resolve or worsen as a complication of the procedure.
• The cause of pain/other symptoms sometimes cannot be found, if you are having an exploratory operation.

**Significant risks and procedure options:**

**Risks of not having this procedure:**

**Anaesthetic:**

**Patient consent:**

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

I acknowledge that the doctor has explained;

• My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
• The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
• Other relevant procedure/ treatment options and their associated risks.
• I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
• My prognosis and the risks of not having the procedure.
• That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
• The procedure may include a blood transfusion.
• Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
• If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
• A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
• I have been given the following Patient Information Sheet/s or explained verbally to me:
  o About your Anaesthetic.
  o About Laparoscopy
  o Blood & Blood Products Transfusion
• I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
• I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
• I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
• I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
• I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

**On the basis of the above statements, I request to have the procedure**

Name of Patient: ........................................... Signature: ....................................... Date: ......................

Signature of Doctor: ............................................................... Signature of witness: ..........................
Section – II  Consent form for Gynaecologic Surgery Procedures  
Informed consent form for Burch Colpo-Suspension

Family name: ...........................................................................................................
Given name(s): ......................................................................................................
Address: ................................................................................................................
Date of birth/Age: ............ Sex: M /F

Condition and procedure:
This condition requires the following procedure. ((Doctor to document in patient’s own words)

The following will be performed:
The cut is made across the upper edge of the pubic hair. This allows the surgeon to get to the bladder neck.
Stitches are placed in tissues next to the bladder neck. This is to hang it from ligaments on the front of the pelvic bone. These stitches will support the bladder neck. This has a very high success rate (better than 9 in 10 women) of treating genuine stress Incontinence. This falls to a high success rate in the coming years. If required, this is followed by looking into the bladder to make sure no damage has been done (cystoscopy).

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
- Infection can occur, requiring antibiotics and further treatment.
- Allergic reaction can occur from medicines or by blood transfusion.
- Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
- Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
- Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
- Heart attack or stroke could occur due to the strain on the heart.
- Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organs.
- Injury to urinary bladder/ureter or the urethra may require further surgery.
- A rupture (hernia) through the top of the vagina. Sometimes further surgery is needed if the hernia becomes large enough.
- Haemorrhage from large arteries and veins about the bladder, vagina and pelvis. This may require a blood transfusion and further surgery.
- Infection in the operation site, pelvis or urinary tract. This may require treatment with antibiotics.
- Problems with passing urine. This is rare, but may need long term care. If this does happen, you may have to pass a tube (catheter) into your bladder to drain the urine.
- There is a higher risk in smokers. This may cause wound and chest infections, heart and lung problems and blood clots in the veins.

Specific risks:
- The bladder may be over-active after the operation. You may need to go to the toilet a lot, may have sudden urge to pass urine and may leak urine. These symptoms may be controlled by bladder retraining and drug therapy. The drug therapy is then slowly cut back. Injury to urinary bladder/ureter or the urethra may require further surgery.
- A rupture (hernia) through the top of the vagina. Sometimes further surgery is needed if the hernia becomes large enough.
- Haemorrhage from large arteries and veins about the bladder, vagina and pelvis. This may require a blood transfusion and further surgery.
- Infection in the operation site, pelvis or urinary tract. This may require treatment with antibiotics.
- Problems with passing urine. This is rare, but may need long term care. If this does happen, you may have to pass a tube (catheter) into your bladder to drain the urine.
- There is a higher risk in smokers. This may cause wound and chest infections, heart and lung problems and blood clots in the veins.

Significant risks and procedure options: .................................................................
Risks of not having this procedure: .................................................................
Anaesthetic: ........................................................................................................
The likelihood of success of above procedure is: Good / fair / poor
Patient consent:
I request Dr. ...................................................... to perform upon me the above mentioned procedure.
I acknowledge that the doctor has explained;
- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/ treatment options and their associated risks.
- I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  o About Your Anaesthetic
  o Blood & Blood Products Transfusion
  o About Burch Colpo-suspension
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: .......................................................... Signature: ........................................ Date: ....................

Signature of Doctor: .......................................................... Signature of witness: .....................................
Section – II  
**Consent form for Gynaecologic Surgery Procedures**

**Informed Consent form for Excision of a Bartholins Gland**

Family name: .................................................................Given name(s): .................................................................
Address: ........................................................................................................ Date of birth/Age: ............... Sex: M /F

**Condition and procedure:**
This condition requires the following procedure. (*Doctor to document in patient’s own words*)

The following procedure will be performed:
This procedure is a surgical incision and drainage of a Bartholin’s cyst or abscess.

**General risks of an excision of a Bartholins gland**
- Infection can occur, requiring antibiotics and further treatment.
- Allergic reaction can occur from medicines or by blood transfusion.
- Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
- Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
- Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
- Heart attack or stroke could occur due to the strain on the heart.
- Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
- Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
- Cardiac arrest & Death as a result of this procedure is possible.

**Specific Risks:**
- The patency and function of the duct may not return to normal in approximately 20% of cases.
- Recurrence of abscess or cyst is common and will need a repeat procedure.
- A malodorous discharge may continue for some time. This may require long term wound dressings.
- There is increased risk in smokers of wound and chest infections, heart and lung complications and thrombosis.

**Significant risks and procedure options:** ........................................................................................................

**Risks of not having this procedure:** ........................................................................................................

**Anaesthetic:** ........................................................................................................

**The likelihood of success of above procedure is:** Good / fair / poor

**Patient consent:**
I request Dr. .............................................................................. to perform upon me the above mentioned procedure.
I acknowledge that the doctor has explained;
- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/ treatment options and their associated risks.
- I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.

STANDARDISED INFORMED CONSENT FORM (ASSOCIATION OF FELLOW GYNECOLOGIST, MUMBAI)
REV1.1 - YEAR 2014.
• Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
• If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
• A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
• I have been given the following Patient Information Sheet/s or explained verbally to me:
  o About Your Anaesthetic
  o Excision of a Bartholins Gland
  o Blood & Blood Products Transfusion
• I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
• I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
• I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
• I accept that medicine is not an exact science and understand that no guarantees can be given as to the results. Understanding these limitations.
• I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: .......................................................... Signature: .................................................. Date: .........................

Signature of Doctor: .......................................................... Signature of witness: ..........................................

STANDARDISED INFORMED CONSENT FORM (ASSOCIATION OF FELLOW GYNECOLOGIST, MUMBAI) REV1.1 - YEAR 2014.
Informed Consent for Cone biopsy of cervix

Family name: .........................................................Given name(s): ..........................................................
Address: ............................................................... Date of birth/Age: ............. Sex: M /F

Condition and procedure:
This condition requires the following procedure. (Doctor to document in patient’s own words).

The following procedure will be performed:
The end of the cervix is surgically removed. The end of the cervix is examined by pathologist for any unusual conditions in the area and further treatment is then given as needed.

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
- Infection can occur, requiring antibiotics and further treatment.
- Allergic reaction can occur from medicines or by blood transfusion.
- Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
- Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
- Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
- Heart attack or stroke could occur due to the strain on the heart.
- Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
- Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
- Cardiac arrest & Death as a result of this procedure is possible.

Specific Risks:
- Damage and narrowing of the cervix may occur which can cause painful periods and difficulty in labour.
- The cervix may not be competent and cause problems with early pregnancy loss.
- Haemorrhage from the cervix, which may need blood transfusion or further surgery, either initially or within weeks of the procedure.
- Infection may be introduced into the uterus or tubes or abdomen. This may require treatment with antibiotics.
- There is increased risk in obese people of wound infection, chest infection, heart and lung complications and thrombosis.
- There is increased risk in smokers of wound and chest infections, heart and lung complications and thrombosis.

Significant risks and procedure options: ..........................................................

Risks of not having this procedure: ..............................................................

Anaesthetic: ...........................................................................................................

The likelihood of success of above procedure is: Good / fair / poor

Patient consent:
I request Dr. .......................................................... to perform upon me the above mentioned procedure.
I acknowledge that the doctor has explained;

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
• The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
• Other relevant procedure/ treatment options and their associated risks.
• I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
• My prognosis and the risks of not having the procedure.
• That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
• The procedure may include a blood transfusion.
• Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
• If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
• A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
• I have been given the following Patient Information Sheet/s or explained verbally to me:
  o About Your Anaesthetic
  o Blood & Blood Products Transfusion
  o About Cone Biopsy
• I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
• I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
• I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
• I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
• I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: ....................................................... Signature: ................................................. Date: ...........................

Signature of Doctor: .................................................................................................. Signature of witness: ...........................................
Section II  Consent form for Gynaecologic Surgery Procedures

Informed Consent for Dilatation & Curettage

Family name: ........................................................................................................... Given name(s): ........................................................................................................
Address: .............................................................................................................. Date of birth/Age: ................. Sex: M / F

Condition and procedure:
This condition requires the following procedure. (Doctor to document in patient’s own words)
........................................................................................................................................
........................................................................................................................................

The following procedure will be performed:
After widening / dilating the cervix (the neck of the womb), an instrument attached to suction is passed into
the uterus (womb). The lining of the uterus and any other tissue that looks abnormal inside the uterus is
then removed and may be sent to pathology for tests.

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
• Infection can occur, requiring antibiotics and further treatment.
• Allergic reaction can occur from medicines or by blood transfusion.
• Bleeding could occur and may require a return to the operating room. Bleeding is more common if you
  have been taking blood thinning drugs.
• Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and
  physiotherapy.
• Increased risk in obese people of wound infection, chest infection, heart and lung complications, and
  thrombosis.
• Heart attack or stroke could occur due to the strain on the heart.
• Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go
to the lungs and produce damage to organ
• Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
• Cardiac arrest & Death as a result of this procedure is possible.

Specific Risks:
• Damage or tearing of the cervix. This may need repair. It can also possibly lead to early pregnancy loss
  in future pregnancies.
• Damage to the uterus due to a perforation (puncture) and possible bowel damage. This may need more
  surgery and a longer hospital stay than expected.
• Severe bleeding (haemorrhage) from the uterus. This may need a blood transfusion.
• Infection in the uterus and tubes. This may need antibiotics.
• The tissue inside the uterus may not all be removed. This may need further surgery.
• Rarely air may get into the blood stream. This air embolism can cause the heart to stop. This can be
  fatal.
• After the procedure is performed, there may be bleeding for up to 10 to 14 days.
• Your first period after the procedure may be late. It may be longer or shorter than usual. There may be
  more or less than the usual amount of blood loss.
• There is higher risk in smokers of chest infection, heart and lung problems and blood clots in the veins.

Significant risks and procedure options: .................................................................
Risks of not having this procedure: .............................................................
Anaesthetic: ...........................................................................................................

The likelihood of success of above procedure is: Good / fair / poor
Patient consent:
I request Dr. ................................................................. to perform upon me the above mentioned procedure.
I acknowledge that the doctor has explained;

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/ treatment options and their associated risks.
- I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  - About Your Anaesthetic
  - About D & C
  - Blood & Blood Products Transfusion
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: ............................................................... Signature: .................................................. Date: .........................

Signature of Doctor: ............................................................. Signature of witness: .................................
Section II
Consent form for Gynaecologic Surgery Procedures

Informed Consent for Diagnostic hysteroscopy and D & C

Family name: …………………………
Given name(s): …………………………………………………
Address: …………………………………
Date of birth/Age: ……………
Sex: M /F

Condition and procedure:
This condition requires the following procedure. ((Doctor to document in patient’s own words)

The following procedure will be performed:
Under an anaesthesia, the cervix is carefully dilated until there is enough room to pass a telescope into the womb. The womb is then filled with fluid/gas, which gives a better view of the inside. A telescope is used to see if there is anything abnormal inside the womb. The fluid is then drained out. The lining of the womb is usually scraped to collect tissues. The lining of the uterus and any other tissue that looks abnormal inside the uterus is then removed and may be sent to pathology for examination.

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
• Infection can occur, requiring antibiotics and further treatment.
• Allergic reaction can occur from medicines or by blood transfusion.
• Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
• Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
• Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
• Heart attack or stroke could occur due to the strain on the heart.
• Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
• Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
• Cardiac arrest & Death as a result of this procedure is possible.

Specific risks:
• Bleeding that can be so heavy that a blood transfusion may be needed. It may also need further surgery.
• Damage may occur to the uterus with rupture or perforation. This may require a laparoscopy and/or laparotomy, and/or longer stay in hospital than expected. In the event of uterine perforation, there is a risk of damage to other organs, such as bowel or bladder, which may require further corrective surgery.
• Rarely, the procedure may not be able to be completed, due to narrowing of the inside of the cervix. If the condition continues, further surgery will be necessary.
• Infection can occur in the uterus. This can cause heavy bleeding or discharge, worsening cramps or high fevers. The infection may affect the fallopian tubes and cause problems with getting pregnant in the future. Antibiotics are used to treat the infection.

Significant risks and procedure options: ...........................................................
Risks of not having this procedure: ...........................................................
Anaesthetic: .................................................................................................

The likelihood of success of above procedure is: Good / fair / poor
**Patient consent:**
I request Dr. ....................................................... to perform upon me the above mentioned procedure.

I acknowledge that the doctor has explained;
- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/ treatment options and their associated risks.
- I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  - About Your Anaesthetic
  - About Diagnostic Hysteroscopy & D and C
  - Blood & Blood Products Transfusion
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

**On the basis of the above statements, I request to have the procedure**

Name of Patient: .................................................. Signature: ........................................ Date: ....................

Signature of Doctor: .......................................................... Signature of witness: .................................
Section – II  Consent form for Gynaecologic Surgery Procedures
Informed Consent for Endometrial Resection/ Ablation

Family name: .................................................................Given name(s): ........................................................
Address: ........................................................................Date of birth/Age: ............ Sex: M /F

Condition and procedure:
This condition requires the following procedure. ((Doctor to document in patient’s own words)

The following procedure will be performed:
The cervix is dilated and an instrument is passed through the cervix into the uterus. The lining of the uterus
is then removed using electric current (diathermy) or other methods.

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
• Infection can occur, requiring antibiotics and further treatment.
• Allergic reaction can occur from medicines or by blood transfusion.
• Bleeding could occur and may require a return to the operating room. Bleeding is more common if you
  have been taking blood thinning drugs.
• Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and
  physiotherapy.
• Increased risk in obese people & smoker of wound infection, chest infection, heart and lung
  complications, and thrombosis.
• Heart attack or stroke could occur due to the strain on the heart.
• Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go
  to the lungs and produce damage to organ
• Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
• Cardiac arrest & Death as a result of this procedure is possible.

Specific risks:
• The procedure may not be able to be completed, due to narrowing of the cervical canal or problems
  inside the uterus. This may need further surgery or surgery abandoned.
• Damage to the uterus with perforation by the diathermy instrument, can cause bleeding and may need
  further surgery to repair the damage. Injuries may not be recognised at time of surgery.
• Damage, by burning, to bowel or bladder. This will need further surgery and a longer than expected stay
  in hospital. Adhesions may result and a colostomy may be needed. Injuries may not be recognised at
  time of surgery.
• Infection could be introduced into the uterus or tubes or abdominal cavity. This may need treatment
  with antibiotics.
• The excessive bleeding (Haemorrhage) from the uterus or blood vessel can occur. A catheter may be
  passed into the uterus to provide balloon pressure to the wall of the uterus for a few hours to control
  bleeding. Blood transfusion, further surgery and possibly hysterectomy may be necessary if the bleeding
  doesn’t stop.
• The distending fluid used to stretch the uterus can be absorbed causing coma or death. Both are
  extremely rare.
• There is risk of failure of procedure in short or long term
• Possibility of pain, and/or bleeding which may get worse after the procedure, and may be long term.

Significant risks and procedure options: .................................................................
Risks of not having this procedure: .................................................................
Anaesthetic: ........................................................................................................
The likelihood of success of above procedure is: Good / fair / poor

STANDARDISED INFORMED CONSENT FORM (ASSOCIATION OF FELLOW GYNECOLOGIST, MUMBAI)
REV1.1 - YEAR 2014.
**Patient consent:**
I request Dr. ............................................................... to perform upon me the above mentioned procedure.

I acknowledge that the doctor has explained;

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/ treatment options and their associated risks.
- I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  - About Your Anaesthetic
  - Blood & Blood Products Transfusion
  - About Endometrial Resection/ Ablation
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

**On the basis of the above statements, I request to have the procedure**

Name of Patient: ............................................................... Signature: .......................... Date: ......................

Signature of Doctor: ............................................................... Signature of witness: .............................
Section – II  Consent form for Gynaecologic Surgery Procedures

Informed Consent for LLETZ of the Cervix

Family name: .................................................................Given name(s): .................................................................
Address: ........................................................................................................Date of birth/Age: ............ Sex: M /F

Condition and procedure:
This condition requires the following procedure. (Doctor to document in patient’s own words)
........................................................................................................................................................................

The following procedure will be performed:
A large loop excision of the transformation zone (LLETZ) is where a small piece of the cervix is cauterised (burnt) with an electric current.

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.
General risks:
• Infection can occur, requiring antibiotics and further treatment.
• Allergic reaction can occur from medicines or by blood transfusion.
• Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
• Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
• Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
• Heart attack or stroke could occur due to the strain on the heart.
• Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
• Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
• Cardiac arrest & Death as a result of this procedure is possible.

Specific Risks:
• Excessive bleeding from the cervix, which may need blood transfusion or further surgery, either initially or within weeks of the procedure.
• Future pregnancies, usually around 20 weeks of pregnancy, may suffer from weakness of the cervix to support a growing pregnancy. This is an uncommon risk.
• Infection may be introduced into the cervix, uterus, tubes or abdomen. This may require treatment with antibiotics.
• Damage and narrowing of the cervix could occur which can cause painful periods and difficulty in labour.
• There is increased risk in smokers of wound and chest infections, heart and lung complications and thrombosis.

Significant risks and procedure options: .................................................................
Risks of not having this procedure: .................................................................
Anaesthetic: ........................................................................................................
The likelihood of success of above procedure is: Good / fair / poor
Patient consent:
I request Dr. ........................................................... to perform upon me the above mentioned procedure.
I acknowledge that the doctor has explained;
• My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
• The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
• Other relevant procedure/ treatment options and their associated risks.
• I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
• My prognosis and the risks of not having the procedure.
• That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
• The procedure may include a blood transfusion.
• Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
• If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
• A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
• I have been given the following Patient Information Sheet/s or explained verbally to me:
  o About Your Anaesthetic
  o Blood & Blood Products Transfusion
  o About LLETZ of the Cervix
• I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
• I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
• I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
• I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
• I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: .......................................................... Signature: .................... Date: ............... 

Signature of Doctor: .......................................................... Signature of witness: ..........................
Consent form for Gynaecologic Surgery Procedures

Informed Consent for Ovarian Cystectomy/ Oophorectomy

Family name: ........................................... Given name(s): ..................................................
Address: .................................................. Date of birth/Age: ............ Sex: M / F

Condition and procedure:
This condition requires the following procedure. (Doctor to document in patient’s own words)

The following procedure will be performed:
  o Laparotomy
  o Laparoscopy
  o Removal of ovary (include side)

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
- Infection can occur, requiring antibiotics and further treatment.
- Allergic reaction can occur from medicines or by blood transfusion.
- Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
- Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
- Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
- Heart attack or stroke could occur due to the strain on the heart.
- Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
- Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
- Cardiac arrest & Death as a result of this procedure is possible.

Specific Risks:
- Severe bleeding can occur therefore blood transfusion may be required to replace blood loss.
- Infection in the operation site or pelvis or urinary tract can occur which may be treated by wound dressings and / or antibiotics.
- Injury to other organs such as the ureter(s) (tube leading from kidney to bladder) bladder or bowel may occur. This is an uncommon risk. Further surgery will be needed to repair the injuries. For bladder injuries, a catheter (plastic tube) may be put into the bladder to drain the urine away until the bladder is healed. For ureteric injury, a plastic tube (stent) is placed in the ureter for 6 weeks and then removed by cystoscopy. If the bowel is injured, bowel resection and a possibility of a temporary or permanent colostomy. A damaged kidney may require removal.
- Bowel blockage after the operation. This may be temporary or in the longer term. Initial treatment may be a drip to give fluids into the vein and no food or fluids by mouth. If it doesn’t get better, bowel surgery may be necessary which may include a colostomy. This can be temporary or permanent.
- The poor early wound healing and the wound may burst open which may require long term wound care with dressings and antibiotics, or a hernia can form in the long term which may need repair by further surgery.
- Wound may heal normally with a thickened scar which may be red and painful. This is called a “keloid” and may be permanent and can be disfiguring.
- Sometimes a small part of the ovary may be left behind and could cause further problems, like pain. & occurrence of other cysts, which may need future surgery.
- Adhesions may form at the site of cyst removal.
- If both ovaries are removed before onset of menopause, risk of osteoporosis and may require therapy eg. hormone replacement therapy.
- Need for oophorectomy when consented for a cystectomy if bleeding excessive or ovary badly damaged.
- There is increased risk in smokers of wound and chest infections, heart and lung complications and thrombosis.

**Significant risks and procedure options:**

**Risks of not having this procedure:**

**Anaesthetic:**

The likelihood of success of above procedure is: Good / fair / poor

**Patient consent:**

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

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/ treatment options and their associated risks.
- I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  - About Your Anaesthetic
  - Blood & Blood Products Transfusion
  - Information leaflet about Ovarian Cystectomy/ Oophorectomy
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

**Name of Patient:** .................................................. **Signature:** ................................. **Date:** ......................

**Signature of Doctor:** .......................................................... **Signature of witness:** .................................
Section – II  Consent form for Gynaecologic Surgery Procedures

Informed Consent for Insertion of
Tension Free sub or mid urethral Vaginal / Trans- obturator Tape
with / without Cystoscopy

Family name: …………………………………………………...
Given name(s): …………………………………………………
Address: …………………………………………………………… Date of birth/Age: ………… Sex: M / F

Condition and procedure:
This condition requires the following procedure. (Doctor to document in patient’s own words)

The following procedure will be performed:
The damaged ligaments are replaced by a 1cm wide tape of synthetic mesh. This tape returns the support for the urethra to the surrounding tissues. This is routinely followed by looking into the bladder to make sure no damage has been done (cystoscopy).

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
• Infection can occur, requiring antibiotics and further treatment.
• Allergic reaction can occur from medicines or by blood transfusion.
• Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
• Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
• Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
• Heart attack or stroke could occur due to the strain on the heart.
• Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
• Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
• Cardiac arrest & Death as a result of this procedure is possible.

Specific Risks:
The success rate is very high (approximately 90%). The long-term success rate is not yet known.
• The bladder may be over-active after the operation. You may need to go to the toilet a lot, may have sudden urges to pass urine and may leak urine. These symptoms are usually managed by bladder retraining and drug therapy. A small proportion of patients will continue to have long standing bladder symptoms despite treatment.
• Problems with passing urine (retention)are uncommon. This rarely needs long term management. If this happens, the tape may be divided through the vaginal cut. There is a small risk of the urinary incontinence returning.
• Infection requiring antibiotics and further treatment.
• Excessive bleeding is very rare.
• There is increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis
• There is a higher risk in smokers. This may cause wound and chest infections, heart and lung problems and blood clots in the veins.
• The urethra or the bladder can sometimes be damaged & require repair.
• The tape may erode through the urethra in the years after the operation. This would need repair of the urethra and a urethral catheter for 2 weeks.
Significant risks and procedure options: .................................................................
Risks of not having this procedure: .................................................................
Anaesthetic: .................................................................................................
The likelihood of success of above procedure is: Good / fair / poor

Patient consent:
I request Dr. ................................................................................................... to perform upon me the above said procedure.
I acknowledge that the doctor has explained;

• My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
• The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
• Other relevant procedure/treatment options and their associated risks.
• I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
• My prognosis and the risks of not having the procedure.
• That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
• The procedure may include a blood transfusion.
• Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
• If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
• A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
• I have been given the following Patient Information Sheet/s or explained verbally to me:
  o About Your Anaesthetic
  o Blood & Blood Products Transfusion
  o About Insertion of Tension Free sub or mid urethral Vaginal Tape & Cystoscopy surgery
• I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
• I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
• I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
• I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
• I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: ................................................................. Signature: .................. Date: .................

Signature of Doctor: ................................................................. Signature of witness: ......................
Section – II  

Consent form for Gynaecologic Surgery Procedures

Informed Consent form for Electric or Cryo cautery to cervix

Family name: …………………………………………………Given name(s): …………………………………………………
Address: ……………………………………………………………………………………………………………………………………………
Date of birth/Age: …………… Sex: M /F

Condition and procedure:
This condition requires the following procedure. (Doctor to document in patient’s own words)
………………………………………………………………………………………………………………………………………………………………
………………………………………………………………………………………………………………………………………………………………

The following procedure will be performed:
The mouth of the cervix having lesion is cauterised with an electrical current/cryo-cautery.

Risks of a electric cautery or cryo cautery to cervix:
There are risks and complications with this procedure. They include but are not limited to the following.

General risk:
• Infection can occur, requiring antibiotics and further treatment.
• Allergic reaction can occur from medicines or by blood transfusion.
• Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
• Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
• Increased risk in obese & smoker people of wound infection, chest infection, heart and lung complications, and thrombosis.
• Heart attack or stroke could occur due to the strain on the heart.
• Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
• Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
• Cardiac arrest & Death as a result of this procedure is possible.

Specific Risks:
• Damage & narrowing of the cervix could occur which can cause painful periods and difficulty in labour.
• In future pregnancies, there is a risk of losing the baby between 16 and 20 weeks of pregnancy. This is an uncommon risk.
• Haemorrhage from the cervix, which may need blood transfusion or further surgery, either initially or within weeks of the procedure.
• There is increased vaginal discharge following cautery, may require some medications & vaginal douching.

Significant risks and procedure options: …………………………………………………………………………………………………………………………………………………………………
Risks of not having this procedure: …………………………………………………………………………………………………………………………………………………………………
Anaesthetic: …………………………………………………………………………………………………………………………………………………………………

The likelihood of success of above procedure is: Good / fair / poor

Patient consent:
I request Dr. …………………………………………………… to perform upon me the above mentioned procedure.
I acknowledge that the doctor has explained;
• My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
• The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
• Other relevant procedure/treatment options and their associated risks.
• I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
• My prognosis and the risks of not having the procedure.
• That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
• The procedure may include a blood transfusion.
• Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
• If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
• A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
• I have been given the following Patient Information Sheet/s or explained verbally to me:
  o About Your Anaesthetic
  o About Electric or cryo Cautery of cervix
  o Blood & Blood Products Transfusion
• I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
• I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
• I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
• I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
• I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: .................................................. Signature: .................. Date: ...........

Signature of Doctor: ........................................................................ Signature of witness: ................................
Consent form for Gynaecologic Surgery Procedures

Informed consent for Vaginal Hysterectomy & Repair

Family name: .......................................................... Given name(s): ..........................................................
Address: ............................................................................................................................... Date of birth/Age: ........... Sex: M /F

Condition and procedure:
This condition requires the following procedure. ((Doctor to document in patient’s own words)

The following procedure will be performed:
Removal of the uterus (womb) through the vagina and repair of any utero- vaginal prolapse.
- Ovaries will also be removed Yes /No
- If yes, which ovaries Left /Right / Both

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
- Infection can occur, requiring antibiotics and further treatment.
- Allergic reaction can occur from medicines or by blood transfusion.
- Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
- Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
- Increased risk in obese or smokers people of wound infection, chest infection, heart and lung complications, and thrombosis.
- Heart attack or stroke could occur due to the strain on the heart.
- Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
- Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
- Cardiac arrest & Death as a result of this procedure is possible.

Specific risks:
- There may be severe bleeding from large blood vessels about the uterus.
- Collection of blood clot at top of vagina (haematoma).
- There may be infection in the operation site or pelvis or urinary tract requiring antibiotics and further treatment.
- Injury may occur to organs such as the ureter(s) (tube leading from kidney to bladder) bladder or bowel. The repair of these organs may be require immediately.
- Fistula may develop between the vagina and other organs (bladder, bowel).
- Bowel blockage can occur after the operation.
- Pain in the perineum, which can last for weeks after surgery.
- Failure after vaginal repair ie. vaginal repair may not be successful, in the short or long term and may need later corrective surgery. This results in recurrence of the prolapse.
- There may be occurrence of pain during sexual intercourse or altered sexual function after vaginal repair surgery.
- Change in bladder and bowel habits can occur occasionally.
- Onset of menopause in pre- menopausal women if both ovaries are removed.

Significant risks and procedure options: ...........................................................
Risks of not having this procedure: ...........................................................
Anaesthetic: ...................................................................................................
The likelihood of success of above procedure is: Good / fair / poor
Patient consent:
I request Dr. ......................................................... to perform upon me the above mentioned procedure.
I acknowledge that the doctor has explained;
- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  - About Your Anaesthetic (Epidural & Spinal Anaesthesia)
  - Blood & Blood Products Transfusion
  - About Vaginal Hysterectomy with repair
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I accept that medicine is not an exact science and understand that no guarantees can be given as to the results. Understanding these limitations.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: ................................................... Signature: ................................................ Date: ....................

Signature of Doctor: ................................................................. Signature of witness: .................................
Section – II  Consent form for Gynaecologic Surgery Procedures

Informed consent for Vaginal Repair

Family name: …………………………………………………… Given name(s): ……………………………………………………
Address: ………………………………………………………………………………………………………………………………………
Date of birth/Age: …………. Sex: M /F

Condition and procedure:
This condition requires the following procedure. (Doctor to document in patient’s own words)

The following procedure will be performed:
Repair of any prolapse through the vagina. This involves a cut in the vaginal area to repair the prolapse of the bladder and / or the rectum (lower bowel) and/or vaginal entrance. It may be necessary to pass a catheter into the bladder after the operation to drain the urine until healing has taken place. Use of mesh or special stich to Sacro-Spinous ligament may be required for vaginal repair.

Risks of a vaginal repair along with mesh and/or with Sacrospinous colpopexy:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
• Infection can occur, requiring antibiotics and further treatment.
• Allergic reaction can occur from medicines or by blood transfusion.
• Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
• Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
• Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
• Heart attack or stroke could occur due to the strain on the heart.
• Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
• Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
• Cardiac arrest & Death as a result of this procedure is possible.

Specific risks:
• Infection in the operation site or urinary tract requires antibiotics and further treatment.
• Injury to other organs such as the ureter(s) (tube leading from kidney to bladder) bladder or bowel.
• Difficulty passing urine immediately following surgery which is usually temporary but which may require a catheter to be reinserted into the bladder, or you may be taught to pass your own catheter until you are able to pass urine without assistance.
• Stress incontinence of urine following surgery. Stress incontinence is a common condition where urine leaks when you cough, sneeze or perform various other activities involving abdominal straining. In this case, whilst no problem existed before surgery, often there is an unknown weakness of the bladder which leads to this problem when surgery is carried out.
• A connection (fistula) may develop between the bladder and the vagina.
• A connection (fistula) may develop between the rectum and the vagina leading to leakage of faeces through the vagina (recto – vaginal fistula).
• Pain in the perineum(area between vagina and rectum), which can last up to six weeks after surgery.
• Change in bladder and bowel habits.
• Narrowing or shortening of the vagina and pain during sexual intercourse.
• Reoccurrence of the original complaint (prolapse) with the passage of time.
• There is increased risk in smokers of wound and chest infections, heart and lung complications and thrombosis.
• Mesh in the form of a permanent or semi permanent artificial support may be used in vaginal repairs to support tissues in this area that are weak. Specific complications with the use of “mesh” are:
  o Infection – this may require removal of the mesh.
Mesh protrusion or erosion – part of the mesh wears through a gap that develops in the vaginal skin so that it pokes out. This will usually require surgery to trim the loose portion and to close the gap in the skin.

- Rejection – loosening of the whole mesh. The mesh may partially or completely protrude through the vaginal skin causing discharge or pain to your partner during sex. This may need another operation to divide the mesh that is protruding out or to remove the entire mesh if there is infection present.

**Significant risks and procedure options:**

**Risks of not having this procedure:**

**Anaesthetic:**

**The likelihood of success of above procedure is:** Good / fair / poor

**Patient consent:**

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

I acknowledge that the doctor has explained:

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/ treatment options and their associated risks.
- I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor/ my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  - About Your Anaesthetic (Epidural & Spinal Anaesthesia)
  - Blood & Blood Products Transfusion
  - About Vaginal repair anterior colporraphy
  - About Vaginal repair posterior colpo-perineorraphy
  - About Vaginal Repair with Mesh
  - About Vaginal Repair- with Sacrospinous Colpopexy
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

**On the basis of the above statements, I request to have the procedure**

Name of Patient: ................................................. Signature: ................................................. Date: .................

Signature of Doctor: .......................................................... Signature of witness: ........................................
Section – II  
Consent form for Gynaecologic Surgery Procedures

Informed consent for Removal of Genital Warts

Family name: …………………………………………………………………………………………
Given name(s): ……………………………………………………………………………………
Address: ……………………………………………………………………………………………
Date of birth/Age: …………… Sex: M /F

Condition and procedure:
This condition requires the following procedure. ((Doctor to document in patient’s own words)
…………………………………………………………………………………………………………………………
…………………………………………………………………………………………………………………………
…………………………………………………………………………………………………………………………

The following procedure will be performed:
Genital warts are soft wart-like growths on the genitals caused by a viral skin disease. They are removed from the genital area by cutting or burning them off.

Risks of removal of genital warts:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
• Infection can occur, requiring antibiotics and further treatment.
• Allergic reaction can occur from medicines or by blood transfusion.
• Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
• Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
• Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
• Heart attack or stroke could occur due to the strain on the heart.
• Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
• Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
• Cardiac arrest & Death as a result of this procedure is possible.

Specific risks:
• The warts may come back (recurrence) and they are usually due to a virus infection, which may cause further warts.
• The area where the wart was removed is an open wound and will take time to heal.
• The area of the wart may be thickened and some discolouring and pain in the scar.
• There is increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
• There is increased risk in smokers of wound and chest infections, heart and lung complications and thrombosis.

Significant risks and procedure options: …………………………………………………………………………………

Risks of not having this procedure: …………………………………………………………………………………

Anaesthetic: …………………………………………………………………………………………………………………
The likelihood of success of above procedure is: Good / fair / poor
Patient consent:
I request Dr. ................................................................. to perform upon me the above mentioned procedure.
I acknowledge that the doctor has explained;
- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/ treatment options and their associated risks.
- I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  - About Your Anaesthetic
  - Blood & Blood Products Transfusion
  - About Removal of Genital Warts
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: ............................................................ Signature: ............................................. Date: .......................

Signature of Doctor: ............................................................ Signature of witness: .................................
Section – II  Consent form for Gynaecologic Surgery Procedures

Informed consent for Insertion of Intra Uterine Device (Cu-T / Progesterone Releasing)

Family name: ………………………………………………….. Given name(s): ………………………………………………….
Address: …………………………………………………………………………………………………………………………… Date of birth/Age: ……….. Sex: M /F

Condition and procedure:
The doctor has explained that you have the following condition:(Doctor to document in patient’s own words)
…………………………………………………………………………………………………………………………………………………. ………………………………………………………………

The following procedure will be performed:
A progesterone releasing intra-uterine device or Cu-T IUD will be put inside the uterus through the vagina.
This will provide long term birth control.

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
• Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs
• Death as a result of this procedure is possible, but very rare.

Specific risks:
• The infection can be passed into the uterus and spread into the pelvis. This may need treatment with antibiotics, and can cause infertility (unable to get pregnant).
• Abnormal bleeding in the first three months may occur. This usually settles its own or some medication can be given to stop bleeding. If not the device may have to be removed.
• Puncture of the wall of the uterus when the intrauterine device is put inside. The device will not work, so pregnancy is possible. There may be infection, which will need antibiotics. The device may need to be removed and a Laparo-Hystroscopy may be necessary to do this.
• The uterus may push out the intra-uterine device in 1 in 20 women. If this happens, pregnancy is a possibility.
• Pain may be felt during and shortly after insertion.
• Ovarian cysts in 1 in 8 women, which may cause pain and painful sex. They usually disappear in 2-3 months. If they persist, further monitoring is required.
• The intra-uterine device may not provide complete relief from the symptoms for which it is being used.
• Pregnancy in 1 in 600 women. A third of these will have an ectopic (tubal) pregnancy. In which case, surgery will be required to remove the foetus and possibly the tube to prevent the tube from rupturing. If the tube ruptures, it can be life threatening and emergency surgery will be required.

Significant risks and procedure options: ...............................................................
Risks of not having this procedure: .................................................................
Anaesthetic: ........................................................................................................
The likelihood of success of above procedure is: Good / fair / poor
Patient consent:
I acknowledge that the doctor has explained;
- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  - About Your Anaesthetic
  - About insertion of IUD
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: .......................... Signature: .................................. Date: ..............

Signature of Doctor: .......................... Signature of witness: ..........................
Section – II  

Consent form for Gynaecologic Surgery Procedures

Informed Consent form for Female Sterilisation

Family name: .................................................Given name(s): .................................................................
Address: .......................................................................................................................... Date of birth/Age: ..........  Sex: M /F

Condition and procedure:
The doctor has explained that you have the following condition: *(Doctor to document in patient’s own words)*
................................................................................................................................................
................................................................................................................................................

The following procedure will be performed:
The operation is usually done Laparoscopically – which is commonly known as keyhole surgery. You will be
given anaesthesia during the operation which may be  a general anaesthetic given by needle into a vein or
under spinal anaesthesia given in the back in spinal cord or under local anaesthesia with sedation. One or
two cuts will be made into your abdominal wall and a gas/air piped into the abdomen in order to lift up the
abdominal wall. A telescope will be put through one of the cuts and sterilising instrument through another.
The cuts will be closed, usually with a dissolvable stitch or sticky tape. Most women go home on the day of
surgery.
Sometime this operation is carried out through small incision in abdomen known as mini-laprotomy.

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risk:
• Infection can occur, requiring antibiotics and further treatment.
• Bleeding could occur and may require a return to the operating room. Bleeding is more common if you
  have been taking blood thinning drugs.
• Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and
  physiotherapy.
• Increased risk in obese people of wound infection, chest infection, heart and lung complications, and
  thrombosis.
• Heart attack or stroke could occur due to the strain on the heart.
• Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go
to the lungs.
• Rarely death as a result of this procedure is possible.

Specific risks:
• This sterilisation operation is intended to make you sterile. You should not have the operation if you are
  uncertain about whether you will want children in the future. It should be assumed that this operation
  cannot be reversed. In some cases, it is possible to re-open the tubes by micro-surgery. Discuss the
  success rate with your doctor. All contraceptive techniques, including sterilisation, have a failure rate.
Pregnancies have even been reported after hysterectomy (removal of the womb). If the tubes are cut,
the removed pieces of tubes will be examined under the microscope to prove sterilisation. There are
risks and complications with this procedure. They include but are not limited to the following.
• Accidental injury to the bowel, blood vessels and the urinary tract. Repair is usually possible at the time
  - often through the small cuts. It may also be necessary to make a larger cut to repair the bowel, blood
  vessel or urinary tract injuries.
• In case of bowel injury, it may be necessary for a temporary colostomy to allow the injured bowel to
  heal. This colostomy would normally be closed at a separate operation a few weeks later.
• Rarely gas, used to inflate the abdomen, can cause heart and breathing problems in 1 in 60,000 women.
  Death is a very rare risk.
• About future pregnancy: The failure rate of the two commonest laparoscopic sterilisations (Filshie clip
  and Fallope ring) is about 1 in 170 to 1 in 250 women who will become pregnant after female
sterilisation. Pregnancy may also happen outside the womb (ectopic pregnancy) and may require emergency surgery. This is rare.

- If the operation cannot be completed through the laparoscope, then open surgery may have to be done. This will mean a larger cut above the pubis – about 5-8 cm, a longer stay in hospital and a longer recovery rate.
- Burns on the skin due to use of electrical equipment in less than 1 in 100 women. These may take a few days to appear.

**Significant risks and procedure options:** …………………………………………………………………………………………………

**Risks of not having this procedure:** …………………………………………………………………………………………………

**Anaesthetic:** ………………………………………………………………………………………………………………………………

**The likelihood of success of above procedure is:** Good / fair / poor

**Patient consent:**
I request Dr. ……………………………………………… to perform upon me the above mentioned procedure.

I acknowledge that the doctor has explained;
- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/ treatment options and their associated risks.
- I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  - About Your Anaesthetic
  - About Female Sterilisation
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

**On the basis of the above statements, I request to have the procedure**

Name of Patient: .......................................................... Signature: .................................................. Date: ......................

Signature of Doctor: ............................................................................................................. Signature of witness: ..........................

STANDARDISED INFORMED CONSENT FORM (ASSOCIATION OF FELLOW GYNECOLOGIST, MUMBAI)
REV1.1 - YEAR 2014.
## Annexure-1

**CHECKLIST TO BE FILLED BEFORE STERILISATION OPERATION OF A MALE OR FEMALE BY THE DOCTOR CONCERNED**

<table>
<thead>
<tr>
<th>No.</th>
<th>Description</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Whether the age of the client is within laid down norms (Male clients should be below the age of 60 years, for female should be below the age of 45 yrs and above 22 yrs)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Whether information relating to marital status, No. of living children and age of the youngest child obtained</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Whether the client has been counseled regarding sterilization so as to help the clients make informed and voluntary decision</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Consent form, Whether the client has understood the consent for and following relative contraindications</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Whether the client has been examined for excluding medical contraindications i.e. psychiatric disorder and physical illness. The surgeon / doctor should examine for the following relative contraindications a) Psychiatric disorder b) Physical illness i) Acute febrile illness ii) Jaundice or other chronic liver disease iii) Anaemia (haemoglobin less than 8 gm.%): iv) Chronic systemic disease, including tuberculosis, brochial asthma, blood dyscrasias, heart disease, uncontrolled diabetes, hypertension and thyrotoxicosis v) Malignancy vi) Skin conditions, including infection involving operation site vii) Pelvic infection, adhesions or mass viii) Severe nutritional deficiency such as generalized oedema, anaemia, and vitamin deficiency c) Allergy to local anesthesia (alternative anaesthesia or procedure must be provided) d) Gross obesity e) The following conditions in post-partum clients i) Puerperal fever ii) Prolonged rupture of membranes (24 hrs) iii) Pre-eclampsia or eclampsia iv) Ante partum or post-partum haemorrhage resulting in Hb &lt; 8 gm.% v) Trauma to genital tract vi) History of post-partum psychosis</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Whether assessment and screening of client has been done as follows:</td>
<td></td>
</tr>
<tr>
<td>6.1</td>
<td>Whether the client has been physically examined for pulse, Blood pressure, respiratory rate, temperature, body weight, general condition, and nutritional status, auscultation of heart and lung, examination of abdomen, pelvic exam., and other exam. As indicated by clients medical history or general physical exam.</td>
<td></td>
</tr>
<tr>
<td>6.2</td>
<td>Laboratory examination: blood test for haemoglobin, urine analysis for sugar, and albumin and other laboratory examination</td>
<td></td>
</tr>
<tr>
<td>6.3</td>
<td>Final medical assessment of the operating surgeons: whether surgeon has verified of the client including abdominal/pelvic examination before conduction of the surgery</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Whether instruction relating to prevention of infection has been followed?</td>
<td></td>
</tr>
<tr>
<td>7.1</td>
<td>Whether cleaning and fumigation of the OT has been done</td>
<td></td>
</tr>
<tr>
<td>7.2</td>
<td>Proper arrangement for decontamination of articles after surgery is available for items that come in contact with blood or other body fluids by placing in the solution of disinfectant for 10 minutes (surgical instruments, gloves, needles, syringes, cotton gauze etc.)</td>
<td></td>
</tr>
<tr>
<td>7.3</td>
<td>Sterilisation procedure of equipments/ instruments required for surgery has been carried out as laid down in the guidelines</td>
<td></td>
</tr>
</tbody>
</table>

Signature and name of the surgeon ................................................................. Date ........................................

---

STANDARDISED INFORMED CONSENT FORM (ASSOCIATION OF FELLOW GYNECOLOGIST, MUMBAI) REV1.1 - YEAR 2014.
Annexure-2

A. Application for sterilization operation and consent form

Name of Patient: shri/smt..............................................................................................................................
Husband / wife’s name .......................................................................................................................................
Father’s name and address .................................................................................................................................
Operation centre ..................................................................................................................................................

Dear sir / Madam,

Kindly make arrangements for my sterilization operation. My age is ....................... years and my husband/wife’s age is ......................... years.

I am married and husband/wife is alive. We have ................. Male and ............... Female living children. The age of my youngest child is ..................... years. I have decided to undergo sterilization operation independently and on my own without any outside pressure, inducement or force. I am aware that other methods of contraceptions are available to me. I know that for all practical purposes this operation is permanent and that after the operation will be unable to have any more children. I also know that there are still some chances of failure of the operation for which the hospital / institution and operating doctor will not be held responsible by me or my relatives or any other person whomsoever. My wife / husband has not been sterilized previously. I am aware that I am undergoing operation, which carries an element of risk. I have been explained the eligibility criteria for the operation and I affirm that I am eligible to undergo operation according to criteria. I agree to undergo the operation under any type of anesthesia which the doctor thinks suitable for me. After sterilization operation if I get pregnant, then I shall report within four weeks to the doctor / hospitaland will get abortion done free of cost. Under such circumstances, the state government will pay a compensation of RS. 5000/- to me which will be acceptable to me. I know that if I am unable to get the pregnancy aborted within four weeks of pregnancy, then I will not be entitled to claim any compensation from any court of law in this regard. I agree to come for follow-up to the centre / doctor as instructed, failing which I shall be responsible for the consequences, if any.

I have read the above mentioned facts / information* in my own language.

Religion: ..............................................................................................................................
Age: ........................................................................................................................................
Business / occupation: .............................................................................................
Signature of applicant/acceptor: ..............................................................................................................
Signature of witness: ...............................................................................................................................
Full Name and address: ..........................................................................................................................

Shri / smt .......................................................................................................................................................... have been explained other methods of contraception available and the failure associated with other methods have been explained fully.

Signature of counselors: ...........................................................................................................................

B. Certificate of medical officer

I certify that I have satisfied myself that shri / smt ........................................................................................................ is within the eligible age group and is mentally and medically fit for a sterilization operation. There is no evidence that he / she has undergone a sterilization operation previously. I have explained all clauses to the client and that this form has the authority of a legal document.

Signature of operating doctor: ....................................................................................................................
Name and address of doctor: .........................................................................................................................
Signature of medical officer: ........................................................................................................................
Name and address of medical officer: .............................................................................................................

STANDARDISED INFORMED CONSENT FORM (ASSOCIATION OF FELLOW GYNECOLOGIST, MUMBAI)
REV1.1 - YEAR 2014.
C. **Denial of sterilization**

I certify that shri / smt ………………………………………………………………………………………….. is not suitable client for sterilization / re sterilisation for the following reasons.

1. ………………………………………………………………………………………………………………………………….
2. ……………………………………………………………………………………………………………………………….

He / she has been provided the following alternative methods of contraception.

……………………………………………………………………………………………………………………………………

Signature of counsellor or doctor making decision: ………………………………………………………………
Name and address of counselor or doctor: ………………………………………………………………………………
*Counselor can be any health personnel including doctor

D. **For official use only**

To be filled by examining doctor

Note: if the surgeon is himself health examiner, the certificate may be given by him.

Age of client according to appearance: ………………………………………………………………………
Urine analysis for sugar: ………………………………………………………………………………………………
Blood pressure: …………………………………………………………………………………………………………
Whether client has under gone sterilization earlier or not …………………………………………..
As per examination by doctor, the client is mentally and medically fit for sterilization operation.

I have confirmed from client regarding his/her marital status and number of living children. I have explained pros and cons of the sterilization operation to the client and he/she him/her self is mentally ready for operation.

Signature of the client: ………………………………………………………………………………..
Signature of the surgeon: …………………………………………………………………………..
Name of doctor in capital letters: …………………………………………………………………
Present place of posting: …………………………………………………………………………..

E. **Certificate of the surgeon**

I have performed the sterilization operation. During the operation there was no visible signs of earlier sterilization and as per appearance he/she was within the age limit for sterilization. If it is female sterilization the type of operation performed:

Abdominal / Vaginal / Laproscopic / Minilap
General / Local anesthesia used

Signature of the surgeon: …………………………………………………………………………..
Name in capital letters: …………………………………………………………………
Present place of posting: …………………………………………………………………
Economical, social and demographic details of the client undergoing sterilization operation

(Monthly report of the district family welfare bureau should be accompanied by the following performa)

1. Name of client ..............................................................................................................
2. Name of head of family shri/smt ..................................................................................
3. Name of father / husband ..........................................................................................
4. Mohalla ............................................................................................. House no. ............
5. PHC / Urban centre ..................................................................................................
6. Ward ..........................................................................................................................
7. Religion ......................................................................................................................
9. Whether married Yes / NO
10. Age of applicant (completed years) ........................................................................
11. Age of husband / wife (completed years) .................................................................
12. No. of alive children a) Sons ........................................ b) Daughters ....................
13. Age of marriage ....................................................................................................... 
14. Educational qualification:
   a. Husband: Illiterate / literate/primary/junior school/high school/graduate and above
   b. Wife: Illiterate / literate/primary/junior school/high school/graduate and above
15. Difference from the last termination of pregnancy (delivery or abortion) .......... years ........ months

Payment particulars:
Amount given to applicant Rupees ....................... paise ....................................

Signature of applicant .................................................................................................
Name ..............................................................................................................................
Date .........................................................

Follow up

Person concerned with the service of applicant
Name ..............................................................................................................................
post ..........................................................................................................................
Place of appointment ....................................................................................................

1. Promoters
2. Health worker
3. Medical officer PHC
4. Surgeon

If tubectomy method adopted: Abdominal / vaginal / Laproscopic /Laprotomy
Type of anesthesia: General / Local / Spinal

Full name of person going to give follow-up ............................................................
Present address ...........................................................................................................

Other Information

1. Whether any contraception method has been adopted earlier: Yes / No
   If yes, 1) Name of method ...................... 2) Period of method .................................
2. Whether promoter of applicant is regional worker of family welfare programme: Yes / No
   If yes, whether applicant is inhabitant of the jurisdiction of that worker: Yes / No
3. Reason for application of sterilization: Limited family / diseasers / financial / other
I certify that above mentioned particular is correct.
Place ..................................................
Signature & Name and address

STANDARDISED INFORMED CONSENT FORM (ASSOCIATION OF FELLOW GYNECOLOGIST, MUMBAI) REV1.1 - YEAR 2014.
Section – II  Consent form for Gynaecologic Surgery Procedures

Informed Consent for Artificial Insemination (AI/CI/IUI/SIFT/SPF)

Family name: ..................................................Given name(s): .................................................................
Address: .................................................................................................................. Date of birth/Age: .......... Sex: M /F

Condition and procedure:
The doctor has explained that you have the following condition: *(Doctor to document in patient’s own words)*
........................................................................................................................................................................
........................................................................................................................................................................

The following procedure will be performed:
The insemination of the wife artificially with the semen / sperms for achieving conception.

Site of insemination: (tick which is appropriate)
  o Vaginal insemination
  o Intra-cervical insemination
  o Intrauterine insemination
  o Sperm intra fallopian transfer
  o Sperm perfusion of fallopian tubes

With sperms of: (tick which is applicable)
  o Sperms of the Husband
  o Sperms of the Donor

Risks of the AIH or IUI:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
  • Infection can occur, requiring antibiotics and further treatment.
  • Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.

Specific Risks:
There are some risks/ complications, which may happened specifically with this type of procedure. They include but are not limited to the following:
  • We understand that even though the insemination may be repeated as often as recommended by the doctor, there is no guarantee or assurance that pregnancy or a live birth will result.
  • We have also been told that the outcome of pregnancy may not be the same as those of the general pregnant population, for example in respect of abortion, multiple pregnancies, anomalies or complications of pregnancy or delivery.
  • The procedure carried out does not ensure a positive result, nor does it guarantee a mentally and physically normal child.
  • Although serological screening tests are done but there is rare possibility of sexually transmittable infections to women.

Significant risks and procedure options: ...........................................................................................................
Risks of not having this procedure: ............................................................................................................
Anaesthetic: ..................................................................................................................................................

The likelihood of success of above procedure is: Good / fair / poor
Patient consent:
I acknowledge that the doctor has explained;
- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care. There is no guarantee or assurance that pregnancy or a live birth will result.
- The outcome of pregnancy may not be the same as those of the general pregnant population, for example in respect of abortion, multiple pregnancies, anomalies or complications of pregnancy or delivery.
- The procedure carried out does not ensure a positive result, nor does it guarantee a mentally and physically normal child. This consent holds good for all the cycles performed at the clinic.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  - About Your Anaesthetic
  - About Artificial (Intrauterine) insemination (by Husband or Donor sperms)
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure.

Signature of wife: .......................................................... ..........................................................

Signature of Husband: .......................................................... ..........................................................

Signature of Doctor: .......................................................... Signature of witness: ..................................
Section III  Informed consent form
Obstetric surgery
Section III Informed consent form – Obstetric surgery

Informed consent form for caesarean section

Family name:.......................................................... Given name(s): ..........................................................
Address: .............................................................................................................................................
Date of birth/Age: ............. Sex: M /F

Condition and procedure:
This condition requires the following procedure: *(Doctor to document in patient’s own word)*
........................................................................................................................................................
........................................................................................................................................................

The following procedure will be performed:
This operation is to remove the baby from the uterus, which is done by a cut in the lower abdomen and cut in the uterus. The doctor then brings out the baby and occasionally forceps may be needed to help the birth of the baby through the abdominal wound out of the uterus. The placenta will also be removed and the cord cut between the placenta and the baby.

Risks of a caesarean section:
There are risks and complications with this procedure. They include but are not limited to the following.

Common risks and complications (>5%) include:
- Infection in the operation site or pelvis or urinary tract. Treatment may be wound dressings and/ or antibiotics.
- Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
- Treatment is with antibiotics and a drain into the wound for a few days.
- The uterus may not contract properly after the operation. This can lead to excess vaginal bleeding, treated with hormone injection/s to contract the uterus. In severe cases, it may be necessary to remove the uterus, preventing future pregnancies.
- Adhesions (bands of scar tissue) may form and cause bowel obstruction. This can be a short term or a long term complication and may need further surgery.
- Increased risk in obese people & smokers of wound infection, chest infection, heart and lung complications, and thrombosis.

Uncommon risks and complications (1-5%) include:
- Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
- Minor skin cut/s to the baby, more common in breech births when the baby’s bottom is against the wall of the uterus. The baby’s bottom, face or body may be cut when the uterus is cut. This usually heals quickly, treated with a band-aid.
- Injury to other organs such as the ureter/s (tube leading from kidney to bladder) bladder or bowel. Further surgery will be needed to repair the injuries.
- The wound may not heal normally. The scar can be thickened and red and may be painful. This is permanent and can be disfiguring.
- Heart attack or stroke could occur due to the strain on the heart.
- Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off (thrombo-embolism) and go to the lungs which could be fatal.
- The scar may rupture (burst) in future pregnancies or during labour. The risk is highest if the cut is made down the uterus rather than across the lower part of the uterus. Scar rupture can be fatal or lead to hysterectomy as a life saving measure.
- Fertility may be reduced after a caesarean section.

Rare risks and complications (<1%) include:
- For future pregnancies a slightly higher risk of placenta previa. *(The afterbirth lies across the lower part of the womb). This can cause major blood loss and the placenta may grow into surrounding organs such as the bladder. A blood transfusion may be needed. Removal of the uterus and repair of the bladder and other organs may be required.*
o Severe bleeding from large blood vessels about the uterus, which will need emergency surgery to repair the damaged blood vessels. A blood transfusion may be required to replace blood loss.
o Rarely, in severe cases, the uterus may have to be removed, stopping future pregnancies.
o Bowel blockage after the operation. This may be temporary or in the longer term. If it doesn’t get better with initial treatment, bowel surgery may be necessary which may include a colostomy. This can be temporary or permanent.
o Poor wound healing and the wound may burst open which may require long term wound care with dressings and antibiotics, or a hernia can form in the long term. This may need repair by further surgery.
o Death as a result of this procedure is possible.

Significant risks and procedure options: .................................................................

Risks of not having this procedure: ........................................................................

Anaesthetic: ........................................................................................................

The likelihood of success of above procedure is: Good / fair / poor

Patient consent:
I request Dr. ........................................................................................................ to perform upon me the above mentioned procedure.

I acknowledge that the doctor has explained;
• My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
• The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
• Other relevant procedure/ treatment options and their associated risks.
• I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
• My prognosis and the risks of not having the procedure.
• That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
• The procedure may include a blood transfusion.
• Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
• If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
• A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
• I have been given the following Patient Information Sheet/s or explained verbally to me:
  o About Your Anaesthetic (Epidural / spinal anaesthesia)
  o Blood & Blood Products Transfusion
  o About Caesarean section
• I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
• I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
• I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
• I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
• I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: .............................................................. Signature: ........................................ Date: .....................
Signature of Doctor: ................................................................. Signature of witness: ..............................
Section III  Informed consent form – Obstetric surgery

Informed Consent for Removal of Ectopic Pregnancy by Laparoscopy / Laparotomy

Family name: ............................................................Given name(s): ............................................................
Address: ........................................................................................................Date of birth/Age: ............ Sex: M / F

Condition and procedure:
This condition requires the following procedure. *(Doctor to document in patient’s own word)*

The following procedure will be performed:

An ectopic pregnancy is where the pregnancy takes place outside the uterus, usually in the fallopian tube sometime in abdomen or ovarian. This may need to be removed by either a laparoscope (key hole) approach or through a large incision know as laparotomy.

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:

- Infection can occur, requiring antibiotics and further treatment.
- Allergic reaction can occur from medicines or by blood transfusion.
- Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
- Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
- Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
- Heart attack or stroke could occur due to the strain on the heart.
- Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
- Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
- Cardiac arrest & Death as a result of this procedure is possible.

Specific Risks:

- There is severe internal bleeding in the abdomen. This may need blood transfusion or further surgery.
- Damage to bladder, bowel or ureter (drainage tube from kidney to bladder). A larger cut to repair the damage may be necessary. In case of bowel injury, it may be necessary for a temporary colostomy to allow the injured bowel to heal. This colostomy is usually closed by surgery a few weeks later.
- Damage to the womb due to the instruments used to move the womb. A perforation (small hole) can happen in 1 in 100 women and will usually heal without further problem. Very rarely, the uterus is removed if bleeding is life threatening.
- Rarely gas, used to inflate the abdomen, can cause heart and breathing problems in 1 in 60,000 women. Death is a very rare risk.
- Removal of only the pregnancy and not the tube may result in some placenta (afterbirth) being left behind and continue to grow. This is treated with further surgery or medication.
- Ovarian pregnancy may require removal of that ovary completely.
- Future pregnancy: There may be recurrence of ectopic pregnancy.
- A minor wound infection or womb infection, which is treated with antibiotics. More serious infections such as pus collections inside the abdomen are treated in hospital with antibiotics and sometimes further surgery.
- Adhesions (bands of scar tissue) may cause blockage of the bowel and/ or difficulty getting pregnant. This can be a short term or a long-term complication and may need further surgery.
- Abnormal wound healing. The wound can be thickened and red and may be painful.
- Hernia may form where the cuts were made and cause pain and swelling.
- Very low possibility of a fistula (a connecting passage between one area and another) developing.
Significant risks and procedure options: ..............................................................................................................
Risks of not having this procedure: ......................................................................................................................
Anaesthetic: ...........................................................................................................................................................

The likelihood of success of above procedure is: Good / fair / poor

Patient consent:
I request Dr. ................................................................. to perform upon me the above mentioned procedure.
I acknowledge that the doctor has explained:
  • My medical condition and the proposed procedure, including additional treatment if the doctor finds
    something unexpected. I understand the risks, including the risks that are specific to me.
  • The anaesthetic required for this procedure. I understand the risks, including the risks that are specific
    to me.
  • Other relevant procedure/ treatment options and their associated risks.
  • I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
  • My prognosis and the risks of not having the procedure.
  • That no guarantee has been made that the procedure will improve my condition even though it has
    been carried out with due professional care.
  • The procedure may include a blood transfusion.
  • Tissues and blood may be removed and could be used for diagnosis or management of my condition,
    stored and disposed of sensitively by the hospital.
  • If immediate life-threatening events happen during the procedure, they will be treated based on my
    discussions with the doctor or my Acute Resuscitation Plan.
  • A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor
    undergoing further training.
  • I have been given the following Patient Information Sheet/s or explained verbally to me:
    o About Your Anaesthetic
    o Blood & Blood Products Transfusion
    o About Removal of Ectopic Pregnancy by Laparoscopy/ Laparotomy
  • I was able to ask questions and raise concerns with the doctor about my condition, the proposed
    procedure and its risks, and my treatment options. My questions and concerns have been discussed and
    answered to my satisfaction.
  • I understand I have the right to change my mind at any time, including after I have signed this form but,
    preferably following a discussion with my doctor.
  • I understand that image/s or video footage may be recorded as part of and during my procedure and
    that these image/s or video/s will assist the doctor to provide appropriate treatment.
  • I accept that medicine is not an exact science and understand that no guarantees can be given has to
    the results. Understanding these limitations.
  • I certify and acknowledge that I have read this form or had it read to me; that I understand the risks,
    alternatives and expected results of the this procedure and that I had ample time to ask questions and
    to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: ................................................................. Signature: ..................................................Date: .................

Signature of Doctor: ................................................................. Signature of witness: ............................
Section III  Informed consent form – Obstetric surgery

Request and Consent form for MTP (MTP ACT Regulation)

Request Form for M.T.P.

I, the undersigned, Mrs/Miss __________________________ (Name)
Husband’s /father’s Name ________________________________
Dr. _________________________________ request

I request to terminate my pregnancy:
- In order to prevent injury to my physical or mental health.
- In view of the substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped.
- As this pregnancy has resulted from my being raped.
- As the pregnancy has occurred as a result of failure of the contraceptive technique of Intrauterine device / oral pills/condom/ coitus interruptus /periodic abstinence / tubectomy or tubal ligation / vasectomy/ ___________ (any other) employed by us.
- In order to prevent a risk of injury to my physical or mental health by reason of my actual / reasonably foreseeable environment.

Signed in my presence __________________________
Name & signature & address of the witness

Consent Form (C-form) For M.T.P.

I, the undersigned, Mrs. / Miss __________________________ (Name)
Husband’s/Father’s Name ________________________________
Aged ____________ completed years and residing at ____________

Give my free consent for the operation of Medical Termination of my pregnancy by Dr. ______________________________ under ______________________ anesthesia to be administered by Dr. ______________________________ I have been explained and I have understood the procedures proposed to be employed for terminating the pregnancy and for anaesthetizing me along with the likely risks and complications of both these, including the remote possibility of this pregnancy continuing in spite of the procedures employed for terminating it. It also understand that procedures other than the proposed ones or in addition to them for terminating the pregnancy and /or for anaesthetizing may be found necessary or desirable and I consent for them, if the surgeon and /or the anesthetist think them essential and beneficial to me.

Signed in my presence __________________________
Signature

Signature & Name and address of the witness

STANDARDISED INFORMED CONSENT FORM (ASSOCIATION OF FELLOW GYNECOLOGIST, MUMBAI) REV1.1 - YEAR 2014.
(MTP certification as per regulation) (Secret)
Form – I
(See Regulation - 3 of MTP act)

(Name and qualification of the Registered Medical Practitioner in Block Letters)

(Full address of Registered Medical Practitioner)

(Name and qualification of the Registered Medical Practitioner in Block Letters)

(Full address of Registered Medical Practitioner)

I/we hereby give information that I/we terminated the pregnancy of the women referred to above who bear the serial No. ........................................... in the admission Register of the hospital/ approved place. The pregnancy was terminated at ........................................... (here, mention time in weeks) and this report is made within 3 hours of such termination.

Date: ........................................... Signature(s) of registered Medical Practitioner(s)

Place: ...........................................

Strike out whichever is not applicable
Of the reasons specified in item (i) to (v) write the one which is appropriate:-

(i) In order to save the life of the pregnant woman.
(ii) In order to prevent grave injury to the physical or mental health of pregnant women
(iii) In view of the substantial risk that if the child was born it would suffer from such physical or mental abnormalities as to be serious handicapped.
(iv) As the pregnancy is alleged by pregnant women to have been caused by rape.
(v) As the pregnancy has occurred as a result of failure of any contraceptive device or method used by married woman or her husband for the purpose of limiting the number of children.

Note:- account may be taken of the pregnant women’s actual or reasonably foreseeable environment in determining whether the continuance of a pregnancy would involve a grave injury to her physical or mental health
Informed consent for MTP-1st trimester

Family name: .......................................................... Given name(s): ..........................................................
Address: ........................................................................................................ Date of birth/Age: ............. Sex: M / F

Condition and procedure:
The doctor has explained that you have the following condition: (*Doctor to document in patient’s own words*)
........................................................................................................................................................................
........................................................................................................................................................................

The following procedure will be performed:
Dilatation (stretching) of the cervix and removal of the foetus and placenta by curettage using an instrument with suction attached inserted into the uterine cavity.

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
• Infection can occur, requiring antibiotics and further treatment.
• Allergic reaction can occur from medicines or by blood transfusion.
• Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
• Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
• Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
• Heart attack or stroke could occur due to the strain on the heart.
• Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
• Lose of function of any limb or organ or paralysis/paraplegia/quadruplegia.
• Cardiac arrest & Death as a result of this procedure is possible.

Specific risks:
• The haemorrhage could occur from the uterus, which may require treatment with blood transfusion.
• Infection may occur in the uterus and tubes, which will require treatment with antibiotics.
• Removal of the lining of the womb (endometrium) can lead to scarring inside the uterus and may cause difficulty with future fertility.
• Incomplete removal of tissue within the uterus is possible which might lead to the necessity of further surgery.
• Damage or tearing of the cervix which may require repair and possibly lead to early pregnancy loss in future pregnancies.
• Damage to the uterus due to a perforation and possible bowel damage. This may require further surgery including the possibility of resection of bowel which may include a colostomy.
• Damage to fallopian tubes is possible, which will affect fertility and there is a small possibility of damage to bladder and blood vessels which could require further surgery. This may include laparoscopy, laparotomy or hysterectomy, and a longer hospital stay than expected.
• Rarely, air may be introduced into the circulation leading to cardiac arrest.

Significant risks and procedure options: ........................................................................................................

Relevant treatment options include:
• Continue with the pregnancy and keep the baby
• Continue with the pregnancy and have the baby adopted after the delivery.

Risks of not having this procedure: ........................................................................................................

Anaesthetic: ........................................................................................................................................

The likelihood of success of above procedure is: Good / fair / poor
Patient consent:
I request Dr. ....................................................... to perform upon me the above mentioned procedure.
I acknowledge that the doctor has explained;

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/ treatment options and their associated risks.
- I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  o About Your Anaesthetic and/ Epidural & Spinal /Local Anaesthesia
  o MTP first trimester
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: ................................................... Signature: ........................................... Date: .....................

Signature of Doctor: ............................................................ Signature of witness: .................................
Informed consent for MTP-2nd trimester

Family name: ..................................................Given name(s): ..................................................
Address: .......................................................... Date of birth/Age: ............. Sex: M /F

Condition and procedure:
The doctor has explained that you have the following condition: *(Doctor to document in patient’s own words)*

The following procedure will be performed:
Medications and/or catheter will be inserted into the vagina/uterus that will induce labour. The foetus (baby) and placenta will be delivered vaginally. The delivery of the foetus and placenta may take up to 48 hours and rarely, 72 hours.

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
- Infection can occur, requiring antibiotics and further treatment.
- Allergic reaction can occur from medicines or by blood transfusion.
- Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
- Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
- Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
- Heart attack or stroke could occur due to the strain on the heart.
- Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
- Lose of function of any limb or organ or paralysis/paraplegia/quadruplegia.
- Cardiac arrest & Death as a result of this procedure is possible.

Specific risks:
- Incomplete passing of placenta, which may need surgery.
- Excessive bleeding from the uterus, which may require treatment with blood transfusion.
- Infection in the uterus and tubes, which will require treatment with antibiotics.
- Damage or tearing of the cervix, which may require repair and possibly lead to early pregnancy loss in future pregnancies.
- Rupture of the uterus, which may need surgery to either repair it or to remove the uterus and a longer hospital stay than expected.
- Failure of procedure: To bring about the desired termination, a further attempt may then be made, or alternatively, surgery including laparotomy and hysterotomy, where a cut is made in the abdomen and then into the uterus.

Significant risks and procedure options: .......................................................... Relevant treatment options include:
- Continue with the pregnancy and keep the baby
- Continue with the pregnancy and have the baby adopted after the delivery.

Risks of not having this procedure: ..........................................................

Anaesthetic: .................................................................................................

The likelihood of success of above procedure is: Good / fair / poor
Patient consent:
I request Dr. ………………………………. to perform upon me the above mentioned procedure.
I acknowledge that the doctor has explained;
- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/ treatment options and their associated risks.
- I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s:
  o About Your Anaesthetic
  o MTP second trimester
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure
Name of Patient: ............................................ Signature: ............................................ Date: .........................

Signature of Doctor: ............................................................... Signature of witness: .................................
Section III Informed consent form – Obstetric surgery

Informed Consent for Epidural Pain Relief for Labour Pain

Family name: ........................................... Given name(s): .................................................................
Address: ...........................................................................................................................................
Date of birth/Age: ............ Sex: M / F

Condition and procedure:
The doctor has explained that you have the following condition: (Doctor to document in patient’s own words)
........................................................................................................................................
........................................................................................................................................
The following procedure will be performed:
An epidural is given into ‘the epidural space’ of your back by means of a very fine plastic tube which is
inserted through an epidural needle and the needle is removed after the tubing is in place. Low strength
local anaesthetic and other pain relieving drugs are given through the tubing to decrease pain. It works by
blocking the pain signals from reaching your brain. The fine plastic tube is taped to your back and drugs can
be given through this fine tube until your baby is born. This analgesia or anaesthetic takes 15 – 30 minutes to
work.

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

Most Common side effects and complications of epidural analgesia or anaesthetic
• Nausea, vomiting, itching and shivering can occur
• Blood pressure could fall & Headache can occur
• Pain, backache and/or bruising at injection site can occur
• Sometimes the epidural anaesthetic works only partially.
• Problems in passing urine, which is usually temporary.
• Haematoma or bleeding. If you take blood thinning medicines, you are more likely to get a
  haematoma as it may affect your blood clotting. Your anaesthetist will discuss this with you.

Less common side effects and complications of epidural analgesia or anaesthetic
• Severe headache - If this happens you may need to have bed rest for several days. Sometimes a
  ‘blood patch’ is needed to be done to take away this headache.
• A change to a general anaesthetic for Caesarean Section maybe necessary if the epidural/spinal is
  not adequate
• Intense itching or rash can be due to drug allergy.
• Temporary nerve damage is remote possibility.

Uncommon side effects and complications from epidural analgesia or anaesthetic
• Infection around the injection spot.
• Nerve damage due to the needle when doing a block.
• Overdose of drugs.
• Cardiac arrest.
• An existing medical condition getting worse.

Very rare risks
• Permanent nerve damage with possible paralysis.
• Blood clot with spinal cord damage.
• The block may go higher than planned and affect breathing by paralysing the breathing muscles.
• Breakage of needles, catheters etc possibly requiring surgery to remove them.
• Epidural abscess & Meningitis
• Death
Disadvantages of an epidural anaesthetic

- It can slow down the second stage of your labour.
- You are more likely to need forceps or a vacuum extraction to help the baby out.
- Occasionally, your legs may feel very heavy and numb, this makes walking around difficult.

Risks to your baby

Some drugs that are given to you during labour will cross the placenta and appear to have little or no effect on the baby.

**Significant risks and procedure options:** ..........................................................

**Risks of not having this procedure:** ..............................................................

The likelihood of success of above procedure is: **Good / fair / poor**

**Patient consent:**

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

I acknowledge that the doctor has explained;
- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  - About Your epidural pain relief for labour pain
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: .......................................................... Signature: .................................................. Date: ......................

Signature of Doctor/Anesthetist: ..........................................................

Signature of witness: ..........................................................................................
Section III Informed consent form – Obstetric surgery
Informed consent for use of Mesopristol medicine in MTP

Family name: .................................................Given name(s): .................................................................
Address: ........................................................................................................................................
Date of birth/Age: .................. Sex: M / F

Condition and Treatment:
The doctor has explained that you have the following condition:
(Doctor to document in patient’s own words)
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................
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This condition requires the use of drug Misoprostol for ripening of cervix & induction of labour for
the purpose of medical termination of pregnancy. Misoprostol tablets may be administered to you orally or
intra-vaginally.

I have read the information leaflet regarding using this drug. My signature indicates my
acknowledgement of receiving and understanding this information and consent for the use of this
medication for the above purpose.

Misoprostol drug is a synthetic prostaglandin. The Prostaglandins have been used for many years to
soften the cervix of the womb and induce uterine contractions, mainly for the purpose of inducing labour. In
a similar manner, they can induce miscarriage for the purpose of termination of pregnancy, when used in
high doses for less than 20 weeks of pregnancy. It is also used to treat haemorrhage (bleeding) after normal
delivery.

Misoprostol presently is not licensed for the purpose of inducing labour. Tablet Misoprostol 200
microgram, is currently licensed for the treatment of gastrointestinal ulcers in men and non-pregnant
women.

Many international and local trials and research have demonstrated its effectiveness and safety
when used to induce labour for the purpose of medical termination of pregnancy or stillbirth and for
softening the cervix prior to surgical termination of pregnancy.
The Misoprostol is currently widely used around the world for these purposes. It has been shown to be as
effective as other licensed medications, with fewer side effects.

Risks and side effects of Misoprostol
There are risks and side effects with taking Misoprostol drug. They include but are not limited to the
following.

- Common side effects of the medication such as nausea, vomiting, diarrhoea, chills, abdominal cramps,
dizziness and low grade fever.
- Strong, sustained uterine contractions may occur after repeated intra-vaginal doses of Misoprostol.
- In women who have previously had a caesarean section, there have been rare reports of rupture of the
uterine scar associated with Misoprostol induction of labour (risk of 1- 4%). This is not unique to
Misoprostol, and can occur whenever labour is induced or promoted in women with a uterine scar. A
modified lower dose is used to reduce this potential risk. If uterine rupture occurs then an operation is
required to control any bleeding, repair the uterus and deliver the baby but In severe cases,
hysterectomy (removal of the womb) may be needed if bleeding cannot be controlled. As mentioned
above, this can occur with the use of other licensed prostaglandin medications as well.
- If drug is used for the purpose of medical termination of pregnancy there is occasional chance of
abortion failure and the need for surgical intervention for any reason may be aroused.

Significant risks with this medication: ..............................................................................................

Risks of not having this medication: ..............................................................................................
Patient consent:
I acknowledge that the doctor has explained;
- The risks of this medication being used, including the risks that are specific to me, and the likely outcomes.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the medication.
- That no guarantee has been made that the medication/treatment will improve my condition even though it has been carried out with due professional care.
- If immediate life-threatening events happen during the treatment, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- Misoprostal is not licensed for the purpose of induction (starting) of labour but has been found to be as effective and safe as similar, licensed medications in numerous trials (research) and in clinical practice.
- A doctor other than the Consultant may conduct the treatment. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  o Misoprostol Information sheet
- I was able to ask questions and raise concerns with the doctor about the medication, the proposed treatment and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my treatment and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this drug and that I had ample time to ask questions and to consider my decision.
- I have my doctor’s name, address and phone number and know that I can call if I have any questions or concerns.

On the basis of the above statements,
I agree to the use of Misoprostal drug to induce labour for the purpose of medical termination of pregnancy.

Name of Patient: .................................................... Signature: ……………………………….. Date: ....................

Signature of Doctor: ………………………………………………..………………….. Signature of witness: ………………………………..
Section III __Informed consent form – Obstetric surgery

Informed Consent for Cervical Cerclage operation

Family name: .................................................................Given name(s): .................................................................
Address: ................................................................................. Date of birth/Age: .................Sex: M /F

Condition and procedure:
This condition requires the following procedure. (Doctor to document in patient’s own words)
........................................................................................................................................................................
........................................................................................................................................................................

The following will be performed:
The nature of the procedure is to suture the cervix for closure of cervical canal in the operating room under anesthesia, usually an epidural anesthetic. The purpose of the procedure is to prevent early pregnancy loss or miscarriage that could result from a known or suspected incompetent cervix.

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
• Infection can occur, requiring antibiotics and further treatment.
• Allergic reaction can occur from medicines or by blood transfusion.
• Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
• Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
• Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
• Heart attack or stroke could occur due to the strain on the heart.
• Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
• Lose of function of any limb or organ or paralysis/paraplegia/quadriplegia.
• Cardiac arrest & Death as a result of this procedure is possible.

Specific Risks:
There are some risks/ complications, which may happened specifically with this type of surgery. They include but are not limited to the following:
• There is possibility of premature rupture of the fetal membranes (amniotic sac) or loss of fluid that may result in premature labor or infection.
• There is possibility premature labor that may result in the need for hospitalization and medication to attempt to stop labor, or the birth of an immature infant.
• There is possibility of injury to bowel, bladder, ureter or other pelvic or abdominal structures and need for immediate surgery or other additional surgery.
• There is possibility of blood loss necessitating transfusion which carries the risk of exposure to AIDS, hepatitis, and other infectious diseases.
• There is possibility of need for prolonged bed rest and abstention from sexual intercourse for the remainder of the pregnancy.
• There is possibility of difficulty in removal of cervical circlage suture and which may be carried under an anesthetic at the hospital.
• I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

Significant risks and procedure options: .................................................................
Risks of not having this procedure: .................................................................
Anaesthetic: .................................................................

STANDARDISED INFORMED CONSENT FORM (ASSOCIATION OF FELLOW GYNECOLOGIST, MUMBAI)
REV1.1 - YEAR 2014.
The likelihood of success of above procedure is: Good /fair / poor

Patient consent:
I request Dr. ................................................................. perform upon me the above mentioned procedure.
I acknowledge that the doctor has explained;
• My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
• The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
• Other relevant procedure/ treatment options and their associated risks.
• I consent to tackle/operate/remove any additional abnormal pathology encountered during surgery.
• My prognosis and the risks of not having the procedure.
• That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
• The procedure may include a blood transfusion.
• Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
• If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
• A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
• I have been given the following Patient Information Sheet/s or explained verbally to me:
  o About Your Anaesthetic
  o Blood & Blood Products Transfusion
  o About cervical cerclage operation
• I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
• I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
• I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
• I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.

On the basis of the above statements, I request to have the procedure

Name of Patient: ............................................................... Signature: ............................ Date: ..................

Signature of Doctor: ............................................................... Signature of witness: .............................
Section III  Informed consent form – Obstetric surgery

Informed consent for Amniocentesis/ Chorionic Villus Sampling

Family name: ..............................................Given name(s): ...........................................................
Address: .......................................................... Date of birth/Age: ............. Sex: M/F

Condition and procedure:
The doctor has explained that you have the following condition: (Doctor to document in patient’s own words)

The following will be performed:
- Chorionic villus sampling (Abdominal route): A needle is passed through the abdominal wall and through the wall of the uterus (womb) and into the placenta. This is performed with ultrasound guidance. A small piece of placenta is removed and the needle is withdrawn.
- Chorionic villus sampling (vaginal route): A cannula is passed through cervical canal and through the cavity of the uterus (womb) and into the placenta. This is performed with ultrasound guidance. A small piece of placenta is removed and the cannula is withdrawn.
- Amniocentesis: A needle is passed through the abdominal wall and through the wall of the uterus (womb) and into the sac of fluid (amniotic cavity) around the baby. This is performed with ultrasound guidance. A small amount (10-20mls) of fluid is removed and the needle is withdrawn.

Risks of the procedure:
There are risks and complications with this procedure. They include but are not limited to the following.

General risks:
- Infection can occur, requiring antibiotics and further treatment.
- Bleeding could occur and is more common if you have been taking blood thinning drugs.
- Death as a result of this procedure is possible.

Specific risks:
Miscarriage / loss of foetus due to chorionic villus sampling in 1 in 100 women and miscarriage / loss of foetus due to amniocentesis in 1 in 200 women if performed before 20 weeks pregnancy. This may be due to:
- Infection may introduced into the abdominal wall or amniotic fluid, which can cause foetal death / miscarriage.
- Bleeding from the uterine wall or around the foetus (baby), which can cause foetal death / miscarriage.
- Rupture / leakage of fluid from amniotic sac, which can cause foetal death / miscarriage.
- Possible bleeding from foetal (baby’s) circulation into maternal circulation. This could lead to loss of foetus (miscarriage) or development of antibodies against the foetus’ blood. The “Anti D” is given to Rhesus negative women to prevent antibody development.
- Premature labour and delivery may be induced if performed after 20 weeks gestation.
- If there is not enough specimen obtained for testing then second procedure (CVS or Amniocentesis) will be offered.
- There is a 1 or 2 in 100 chance that the result will show that the chromosomes of the placenta are different to that of the foetus. If this happens, a second procedure (Amniocentesis) will be offered to clarify the result.
- Occasionally, the test fails due to unknown reasons, in this situation the test may fail to give a “good enough sample” for chromosome and/or DNA analysis.

Significant risks and procedure options: ........................................................................................................
Risks of not having this procedure: ................................................................................................................
Anaesthetic: ................................................................................................................................................

STANDARDISED INFORMED CONSENT FORM (ASSOCIATION OF FELLOW GYNECOLOGIST, MUMBAI) REV1.1 - YEAR 2014.
Patient consent:
I acknowledge that the doctor has explained;

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/ treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  - Local Anaesthetic for your procedure
  - Amniocentesis/Chorionic Villus Sampling
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: ................................................................. Signature: .................................................. Date: .................

Signature of Doctor: ........................................................................ Signature of witness: ..............................................
FORM OF CONSENT FOR INVASIVE PREGNATAL DIAGNOSTIC TECHNIQUES
(Form G of PCPNDT act)

I, __________________________________________ w/o ____________________________
Age____________ years residing at ____________________________________________
Hereby state that I have been explained fully the probable side effects and after effects of the
prenatal diagnostic procedures.
I wish to undergo the pre-implantation / prenatal diagnostic techniques/test/procedures in my own
interest to find out the possibility of any abnormalities disease/deformity/disorder in my child I am
carrying.
I undertake not to terminate the pregnancy if the prenatal procedure/techniques/test conducted
show the absence of disease / deformity / disorder.
I understand that the sex of the foetus will not be disclosed to me.
I understand that breach of this undertaking will make me liable to penalty as prescribed in pre
natal diagnostic techniques (regulation and prevention of misuse) Act, 1994 (57 of 1994) and rules
framed thereunder.

Date & Place

Signature of pregnant women ..............................................................

I have explained the contents of above to the patient and her companion
(Name_________________________ address ________________________________
relationship ________________________________) in a language she / they understand.

Signature of doctor with Registration no.

Name/ Address/ Registration no. of genetic clinic

Date
Section IV  Miscellaneous consent form
**Section IV  Miscellaneous consent form**

“Perinatal (stillborn baby) Autopsy” Consent Form

Family name: .......................................................... Given name(s): .................................................................
Address: ........................................................................................................... Date of birth/Age: ............ Sex: M /F

**Consent by parent(s) or Substitute Decision-maker:**

I am the ............................................................................................................. (Enter relationship) of the deceased baby
........................................................................................................................ (Enter baby’s name or “baby of mother’s name”) and
I am his / her parent / substitute decision-maker.

- I consent to an autopsy (Post Mortem examination) to find out the reasons why my baby died, and understand that there is a possibility that a cause of death may not be found. I understand that autopsy may, also, be considered for confirmation of ultrasound findings, investigation of possible chromosomal / metabolic abnormalities, obtain tissue for storage for future investigations, or identify a syndrome which may be related to, but not represent, the final event causing death.

- I have been given the opportunity to have a Social Support Person e.g. partner or parent or close friend present during these discussions.

- I have been given and have read and understood the leaflet “Information about perinatal autopsies”. I understand that the more thorough the examination, the more information the final report will contain.

- I consent to a pathologist performing:
  - A full post mortem examination
  - A limited post mortem examination, which only involves the following organs or regions of the body
  - External examination only, which may include x-rays and placental examination

- The practitioner who is obtaining this consent may / may not (please strike out, as appropriate) request further consultation with me in the event that there are unexpected findings in the limited post mortem examination.

- I consent to the pathologist keeping and using tissue samples that have been removed as part of the autopsy for:
  - Medical teaching Yes/ No
  - Research - review of microscope slides to aid future research Yes/ No
  - Quality control (e.g. small tissue samples are useful to show that routine laboratory tests have worked successfully) Yes / No

- I would like the following additional limits put on the autopsy (e.g. “do not examine the head”, “no organs to be kept”): .................................................................

- I consent to the baby’s and mother’s medical record (tick as appropriate):
  - Being provided to the pathologist to enable him / her to do the autopsy
  - Being used to review the treatment which he / she received during life
  - Being used for medical education provided that mother’s and baby’s identity is not revealed.

- I consent to further copies of the completed autopsy report to be sent to the following medical practitioner(s):

- I have been able to ask questions and raise concerns about the autopsy. My questions and concerns have been discussed and answered to my satisfaction.

- I am aware that the autopsy may commence immediately after I give my consent and so it may not be possible to withdraw my consent should I change my mind.

There is a possibility that a cause of death may not be found. Therefore, parents who want to know why their baby has died and consent to an autopsy to find out the reasons may be disappointed and regret their decision about autopsy if a cause of death is not found.

**On the basis of the above statements, I give consent to the autopsy.**

Name of parent / substitute decision-maker: .......................................................... 
Signature: .......................................................... Date: ...........................................
Name of Doctor: .......................................................... Designation: ....................... Signature: .................
Section IV  Miscellaneous consent form

Blood and Blood Products Transfusion Consent

Family name: ......................................................Given name(s): .................................................................
Address: .......................................................... Date of birth/Age: .....................Sex: M /F

This consent primarily includes intravenous or central venous line infusion of fresh blood and blood products, red cells, platelets and plasma (e.g. fresh frozen plasma and cryoprecipitate).
You have a transfusion of blood or blood products, which are from volunteer donors. The blood is collected and screened by Blood Bank having licence from govt. A transfusion is necessary to replace a part of your blood and is given to either;
- To replace red blood cells to treat or prevent anaemia, improve oxygen transport and relieve symptoms of dizziness, tiredness or shortness of breath or
- To give you platelets to help stop or prevent bleeding or
- To give a fresh plasma product to stop, treat or prevent bleeding.

Transfusions are given via needle in your vein or via a central line into your vein. During transfusion you will be closely watched for any possible reactions and will also be regularly checked as to whether you may need another blood transfusion.

The doctor has explained that I have the following medical condition for which I need a transfusion: 
(Doctor to document in patient’s own words)
...............................................................................................................................

Your medical condition requires the following blood product/s.
- Red Cells
- Platelets
- Fresh Frozen Plasma
- Cryoprecipitate

Frequency of the treatments: (Doctor can specify that the frequency may vary during the course of treatment) .................................................................

Start Date of Transfusion _______________________
Approximate End Date of Transfusion ______________

Risks of blood and blood products transfusion:
Most common reactions to fresh blood or blood products that are being transfused are:
- High temperature
- Rash, itching and hives
- Feeling unwell

Rare risks are:
- Having too much blood/fluids giving you shortness of breath.
- Haemolysis, the abnormal breakdown of red blood cells.
- The development of antibodies which may complicate future transfusions and/or organ or tissue transplants. If these complications develop in women they can potentially cause problems for all current and future unborn babies.
- Lung injury causing shortness of breath.
- The spread of viral or other infectious germs from the blood of the donors.
- Very rarely, these above reactions can cause severe harm or possibly death.
- There are specific problems for long term multiple transfusions that may be relevant to your medical Condition which shall be discussed by your doctor.
Other relevant treatment options:
In some situations there may be other choices to a blood transfusion and these include – fluid replacement with saline or other artificial compounds and/or iron supplements. Your Doctor will discuss these with you as some choices are not suitable for everybody.

Risks of not having the blood and/or blood products transfusion:
(Doctor to document in space provided)

Patient consent:
I acknowledge that the doctor has explained;

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  o About Blood Transfusion & Blood components
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the this procedure and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: ................................................................. Signature: ............................... Date: ...................

Signature of Doctor: ............................................................... Signature of witness: ...............................
**Section – IV    Miscellaneous Consent form**

**Informed Consent for Anaesthesia**

Family name: .........................................................Given name(s): .................................................................

Address: ........................................................................................................ Date of birth/Age: ..................Sex: M /F

**Condition and procedure:**

I, acknowledge that my doctor has explained to me that I will have an operation, diagnostic, or treatment procedure. My doctor has explained the risks of the procedure, advised me of alternative treatments, and told me about the expected outcome and what could happen if my condition remains untreated. I also understand that anesthesia services are needed so that my doctor can perform the procedure.

**Risks of the Anaesthesia procedure:**

I understand that these risks apply to all forms of anesthesia. They include but are not limited to the following.

**General risks:**

- Infection can occur, requiring antibiotics and further treatment.
- Allergic reaction can occur from medicines or by blood transfusion.
- Bleeding could occur and may require a return to the operating room. Bleeding is more common if you have been taking blood thinning drugs.
- Small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.
- Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis.
- Heart attack or stroke could occur due to the strain on the heart.
- Blood clot in the leg (DVT) causing pain and swelling. In rare cases part of the clot may break off and go to the lungs and produce damage to organ
- Lose of function of any limb or organ or paralysis/paraplegia/quadruplegia.
- Cardiac arrest & Death as a result of this procedure is possible.

**Specific Risks:**

I understand that the type(s) of anesthesia service checked below will be used for my procedure and that the anesthetic technique to be used is determined by many factors including my physical condition, the type of procedure my doctor is to do, my doctor’s preference, and my own preference. It has been explained to me that sometimes an anesthesia technique which involves the use of local anesthetics, with or without sedation, may not succeed completely and therefore another technique may have to be used including general anesthesia. There are some risks/ complications, which may happened specifically with this type of anaesthesia and surgery. They Include but are not limited to the following: (please tick appropriate box)

<table>
<thead>
<tr>
<th>☐ General Anesthesia</th>
<th>Expected Result</th>
<th>Total unconscious state, possible placement of a tube into the windpipe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technique used</td>
<td>Drug injected into the bloodstream, breathed into the lungs, or administered by other routes</td>
<td></td>
</tr>
<tr>
<td>Specific Risks</td>
<td>Mouth or throat pain, hoarseness, injury to mouth or teeth, awareness under anesthesia, injury to blood vessels, aspiration, pneumonia</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>☐ Spinal or Epidural Analgesia/ Anesthesia With sedation</th>
<th>Expected Result</th>
<th>Temporary decrease or loss of feeling and/or movement to lower part of body</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technique used</td>
<td>Drug injected through a needle/catheter placed either directly into the spinal canal or immediately outside the spinal canal</td>
<td></td>
</tr>
<tr>
<td>Specific Risks</td>
<td>Headache, backache, buzzing in the ears, convulsions, infection, persistent weakness, numbness, residual pain,</td>
<td></td>
</tr>
</tbody>
</table>
### Monitored Anesthesia Care

**With sedation**

**Expected Result**
Reduced anxiety and pain, partial or total amnesia

**Technique used**
Drug injected into the bloodstream, breathed into the lungs, or administered by other routes producing a semi-conscious state

**Specific Risks**
An unconscious state, depressed breathing, injury to blood vessels

**Without sedation**

**Expected Result**
Measurement of vital signs, availability of anesthesia provider for further intervention

**Technique used**
None

**Specific Risks**
Increased awareness, anxiety and/or discomfort

---

**Risks of not having this procedure:** .................................................................

**The likelihood of success of above procedure is:** Good / fair / poor

**Patient consent:**
I request Dr. ................................................................. perform upon me the above mentioned procedure.

I acknowledge that the doctor has explained:
- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- I also consent to an alternative type of anesthesia, if necessary, as deemed appropriate by them.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- That no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.
- I have been given the following Patient Information Sheet/s or explained verbally to me:
  - About Your Anaesthetic
  - Blood & Blood Products Transfusion
• I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.

• I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.

• I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.

• I accept that medicine is not an exact science and understand that no guarantees can be given to the results and understanding these limitations.

BLOOD TRANSFUSIONS during surgery
The likelihood of needing a blood transfusion for this procedure is: (please tick appropriate box)

□ Highly unlikely
□ Possible
□ Probable

I understand that there are potential risks from blood transfusions, though rare, and that some of these include transfusion reaction, hepatitis, and AIDS (Acquired Immune Deficiency Syndrome).

Please tick appropriate box:

□ I give consent to receive blood or blood products as determined by my anesthetist and doctor to be necessary for my well-being.
□ I give consent to receive blood or blood products only as an emergency life-saving measure.
□ I do not want to receive blood or blood products under any circumstance.

I certify and acknowledge that I have read this form or had it read to me; that I understand the risks, alternatives and expected results of the anesthesia service; and that I had ample time to ask questions and to consider my decision.

On the basis of the above statements, I request to have the procedure

Name of Patient: ................................................................. Signature: ............................... Date: ...................

Signature of Doctor: ............................................................... Signature of witness: ...............................
Section IV    Miscellaneous consent form

Discussion and Refusal of Treatment

Patient’s Name: __________________________

I am being provided information and refusal form so I may fully understand the procedure recommended for me and the consequences of my refusal.

Risks of Not Having the Recommended Treatment:
I understand that complications to my Reproductive tract & its function, and/or general health may occur if I do not proceed with the recommended treatment.
These complications include:

__________________________________________________________________________

__________________________________________________________________________

I have had an opportunity to ask questions about these risks and any other risks I have heard or thought about.

Acknowledgement:
I ____________________________________________________________ have received the above information about the proposed procedures. I have discussed my treatment with Dr. ______________________________ and have been given the opportunity to ask questions and have them fully answered.
Dr. ______________________________ has informed me of the need for procedures, alternate treatment options, risks associated with not taking procedures, and my refusal to take procedures.

I personally assume the risks and consequences of my refusal, and release for myself, my heirs, executors, administrators, or personal representatives, those doctors who have been consulted in my case from any and all liability for ill effects which may result from my refusal to consent to the performance of the proposed treatment.
I acknowledge that I have read this document in its entirety, that I fully understand it and that all blank spaces have been completed or crossed off prior to my signing.

I do not wish to proceed with the recommended treatment.

I also understand that Dr. ______________________________ will/may refuse to treat me if I refuse necessary diagnostic or therapeutic proposed procedures.

Patient or Guardian Signature: ______________________________ Date: __________

Treating Doctor Signature: ______________________________ Date: __________

Witness Signature: ______________________________ Date: __________