Guide book for Genetic Counselling
Centres/Genetic Clinics/Genetic Laboratories
under PCPNDT Act
2015

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For further information contact

State Family Welfare Bureau
Kutumb Kalayan Bhavan
Naidu Hospital Compound
Raja Bahadur Main Road
Pune – 411027

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Guide book for Genetic Counselling Centres/Genetic Clinics/Genetic Laboratories under PCPNDT Act

Department of Public Health and National Health Mission Government of Maharashtra

2015

Supported by United Nations Population Fund
MESSAGE

Preference of boy child and discrimination against the girl child is almost universal in India and manifests itself in many ways including the practice of gender biased Sex Selection. This practice has led to the decline in the Child Sex Ratio (CSR) which is calculated as the number of girls per 1000 boys in the 0-6 year’s age group. The CSR in the country declined from 976 in the year 1961 to 918 in the year 2011. Even in Maharashtra the CSR has declined from 978 in 1961 to 894 in 2011.

In order to address the declining sex ratio, Maharashtra has been playing a very proactive role in ensuring that the PCPNDT (Prohibition of Sex Selection) Act, 1994 is implemented effectively and in it’s true spirit.

The State is now attempting to work towards changing mindsets of doctors and clients so as to create a socio-cultural milieu where the girl child is welcome, only then we will be able to halt the decline in Child Sex Ratio.

The medical practitioners have requested the State to prepare a set of guidelines so that they could follow in order to ensure that their clinics are compliant as per the requirements of the PCPNDT Act. It was requested for training programs to be organized for their members in order to make them aware of the Act. This guide book for Genetic Counseling centers, Genetic Laboratories and Genetic Clinics is an attempt towards this end.

(Dr. Deepak Sawant)
MESSAGE

Gender inequalities have existed in India for centuries. This has resulted in discrimination against the girl child at every stage of her life – sex selection; infanticide; in equal access to education, health care, nutrition, child marriage, teenage pregnancies, dowry and various forms of violence.

Declining Child Sex Ratio (Number of girls per 1000 boys in the 0-6 years age group) in Maharashtra is an issue of concern. The CSR in the State declined from 913 in 2001 to 894 in 2011, although the Sex Ratio at Birth (Number of girls born per 1000 boys) has improved from 896 in 2007-09 to 902 in 2011-13.

The state is making various efforts to prevent the decline by creating awareness to change mindsets of people that prefer boys over girls and also working on effective implementation of the Pre Conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994.

This guide book is an attempt to involve owners of Genetic Counselling Centers / Genetic Laboratories / Genetic Clinics to do their bit for implementation of the law.

(Prof. Ram Shinde)
MESSAGE

Maharashtra was the first State in the Country to enact the Maharashtra Regulation of use of Pre-Natal Diagnostic Techniques Act in 1987. This paved the way for the enactment of the Prevention of misuse of Pre-natal Diagnostic Techniques Act in 1994 and the amended Pre Conception and Pre-natal Diagnostic techniques (PCPNDT) Act in 2003.

The Public Health Department, Government of Maharashtra has also been in the forefront in terms of initiating various innovative activities to improve implementation of the PCPNDT Act. Some of the innovations include: registration of all manufacturers, sellers and distributors of ultra sonography (USG) machines with State Appropriate Authority; Numbering of all USG machines with a unique identification code; Provision of monitory support to NGOs and Civil Society organizations for Conducting decoy operations; online submissions of F-Forms; initiating a helpline 18002334475 and a website www.amchimulgi.gov.in for reporting on erring doctors, etc. Maharashtra has also undertaken capacity building of Implementing Authorities like Judicial Officers, Prosecutors, Members of Advisory Committees and Appropriate Authorities.

As a result of our ongoing efforts, the Sex Ratio at Birth (SRB) which is the number of girls born for every 1000 boys in Maharashtra has been showing an improvement. According to SRS the SRB increased from 893 in 2009-11 to 896 in 2010-12 and to 902 in 2011-13. As part of our efforts to address Gender Biased Sex Selection (GBSS) in the state we would also like to build capacities of doctors to enable them understand their role in addressing the issue of skewed Sex Ratio and on making their clinics complaint as per the PCPNDT Act. A comprehensive set of Do's and Don'ts for Genetic Counselling Centers, Genetic Clinics and Genetic Laboratories have been circulated to Professional Medical Association to inturn circulate the same to their members.

This guide book is also an attempt to inform doctors on basic issues under the PCPNDT Act. The guide book also makes an attempt to answer certain frequently asked questions by owners of Genetic Clinics. I would like to congratulate National Health Mission, State Family Welfare Bureau and IRIA Maharashtra Chapter for providing their valuable inputs for this guide book. I would also like to compliment the United Nations Population Fund for providing the necessary technical support for bringing out the guide book. I hope the guide will be extensively used by all USG Centers.

(Sujata Saunik)
Principal Secretary, PHD
Foreword

In order to address the issue of sex selection efforts are required on multiple fronts. On the one hand we need to work on addressing structural inequalities and patriarchy so as to improve the position of women and girls; on the other hand we need to intensify implementation of the Pre Conception and Pre-natal Diagnostic Techniques Act. National Health Mission has been working on both these above issues.

As part of our various efforts we are also working on involving the medical community to strengthen their efforts to prevent sex selection.

The guide book for Genetic Counselling Centers / Genetic Laboratories / Genetic Clinics is an attempt to provide information to these centers on what is expected from them under the PCPNDT Act. The document is dated and includes reference to Government Orders, Amendments up to June 30th 2015.

I would like to acknowledge the efforts of Ms. Anuja Gulati, UNFPA and Dr. Asaram Khade, Consultant PCPNDT, GOM, in bringing out this guide book.

(Signature)

(I. A. Kundan I.A.S.)
Commissioner (FW) & Mission Director,
National Health Mission, Maharashtra, Mumbai
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Gender biased Sex Selection is a complex issue emanating from a web of social, economic and cultural factors which include preference of sons over daughters, access to and availability of technology and its misuse and the desire of couples to have smaller families but not without sons. This practice has existed in India for centuries but has now assumed alarming proportions. The Child Sex Ratio (CSR) which is calculated as number of girls per 1000 boys in the 0-6 years age group has shown a steep decline. The CSR in India declined from 976 in 1961 to 918 in 2011. In Maharashtra the CSR declined from 978 in 1961 to 894 in 2011. It is estimated that in India the practice of sex selection has led to the loss of approximately 4.56 lakh girls annually during the period 2001-2012, indicating that 3.6% of female births out of total female births did not occur due to the practice of sex selection. In Maharashtra 43,952 girls have gone missing at birth annually over the last twelve years which is around 4.8% of the total female births*.

The obsession for a son often is the reason behind tremendous psychological pressure on women. Such pressure also manifest itself in the form of bigamy and desertion for women’s perceived inability to bear a male child impacting their reproductive, mental and physical health. Evidence from states with skewed sex ratios has shown that the practice of Gender Biased Sex Selection could lead to increased violence against women, bride trafficking and a resurgence of practices such as polyandry.

* UNFPA, How many girls are missing at birth in India? Trends in Sex Ratio at Birth (2001-12), UNFPA July 2015
In order to address the issue of declining Child Sex Ratio, the Government of India in 1994 passed The Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, (PNDT) prohibiting sex selection for non medical reasons and regulating pre-natal diagnostic techniques such as ultrasonography. The Act was subsequently amended in 2003 to include prevention of use of Pre Conception diagnostic techniques and was called the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act. (PCPNDT)

The amended Act prohibits determination and disclosure of the sex of the foetus and bans advertisements related to preconception and pre-natal determination of sex. The Act also makes it mandatory for all ultrasound clinics and other diagnostic facilities capable of sex determination, to prominently display a signboard that clearly indicates that disclosure of the sex of the foetus is illegal. Further, all such facilities have to be registered with the Appropriate Authority. The Act also mandates manufacturers to provide information to the government about the sale of ultrasound machines and other similar equipment.

The issue of Gender Biased Sex Selection is critical and needs to be addressed systematically by different partners, the medical community being a critical partner. This guide book is meant for Genetic counselling centres, Genetic clinics and Genetic Laboratories who come under the purview of the PCPNDT Act. It provides the medical community with basic information on what is expected from them under the Act and also attempts to answer frequently asked questions related to Act compliance. The document is dated and includes references to Government orders and Amendments upto 30th June 2015.
REGISTRATION OF CENTRES

As per the PCPNDT Act, all places using pre-conception and sex selection techniques/procedures and any place having equipment capable of detecting sex of the foetus and those related to genetic counseling have to be registered. The procedure for obtaining registration is also laid down in the Act. To qualify for registration, the applicant organization must fulfill the requirements of space, equipment, employees and standards as specified in the Act.

The registration is binding on government and semi government institutions, whether privately or publicly owned. There is no exemption for any institution on the grounds of it being under Central, State or Local Government or on the basis of it being a charitable or cooperative organization or any other grounds. Similarly, all facilities having ultra-sonography for the purpose of pre-natal diagnosis or for any other purpose also come under the purview of the Act and have to be registered with the Appropriate Authority. This chapter deals with all aspects related to registration of clinics.

Section 18(1) of the PCPNDT Act states that “No person shall open any Genetic Counselling Centre, Genetic laboratory or Genetic Clinic including clinic, laboratory or centre having ultrasound or imaging machine or scanner or any other technology capable of undertaking determination of sex of foetus and sex selection or render services to any of them after the commencement of the Pre-natal Diagnostic Techniques (Regulation and prevention of misuse) Amendment Act, 2002, unless such centre, laboratory or clinic is duly registered under the Act”.
1. How to apply for registration of an ultrasonography (USG) clinic / Genetic Counselling Centre/Genetic Laboratory/Imaging Centre?

Section 18(2) of the PCPNDT Act states that every application for registration under subsections (1) shall be made to the Appropriate Authority (In Maharashtra Civil Surgeons and Medical Officers of health have been designated as Appropriate Authorities for Districts and Corporations respectively) in Form A. This form has to be accompanied by fees as prescribed under the Act.

2. What are the documents to be submitted to Appropriate Authority for grant of registration?

Rule (4) of the PCPNDT Act states that “An application for registration shall be made to Appropriate Authority in duplicate in Form A”. Form A is enclosed as Annexure 1.

Form A should be accompanied by:

i. An affidavit containing an undertaking to the effect that the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre or a combination thereof as the case may be shall not conduct any test or procedure by whatever name called for selection of sex before or after conception or for detection of sex of foetus, except for diseases specified in section 4 (2), nor shall the sex of the foetus be disclosed to anybody as per Rule 4(i). The affidavit should be signed by the person who would be performing sonography. A sample of the affidavit form is enclosed as Annexure 2.

ii. An undertaking to the effect that the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Combination thereof, as the case may be, shall display prominently a notice stating that they do not conduct any technique, test or procedure, by whatever name called for detection of sex of foetus or for selection of sex before or after conception as per Rule 4(ii)
iii. Degree of certification of doctor/certificate of having undergone 300 hours training titled “Fundamentals in Abdomino-Pelvic Ultra sonography (As per Amendment dated 9-1-2014)
iv. Certificate of registration of doctor with State Medical Council (both Under Graduate and Post Graduate)
v. Details of place where centre is to be established
vi. Details of machine (make, model, serial number)
vii. Registration fee – Rs.25,000/- for Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/ Imaging Centres and Rs.35,000/- for centre providing two or more services as per Rule 5 (Amendment dated 4-6-2012)

3. **How is the registration fee to be paid?**

Rule 5(2) states that the application fee shall be paid by a demand draft drawn in favor of the Appropriate Authority on any scheduled bank payable at the headquarters of the Appropriate Authority concerned.

The payee name on the demand draft should be Civil Surgeon/Medical Officer of Health (Location).

4. **Is there any additional paper work for hospitals registered as Trust hospitals, Company hospitals or Nursing Homes?**

Yes, such hospitals should submit to the Appropriate Authorities along with application for registration, their registration certificate from competent authority (for e.g. Trust hospital will give its certificate of registration received from charity commissioner).

5. **What is the process for granting certificate of registration?**

As per Section 19(1) and Rule 6(1) The Appropriate Authority shall, after making such enquiry and after satisfying itself that the applicant has complied with all
the requirements of the Act and Rules under it, place the application before the Advisory Committee for its advise.

As per Rule 6(2) having regard to the advice of the Advisory Committee, the Appropriate Authority shall grant a certificate of registration in duplicate in form B (enclosed as Annexure 3) to the applicant (Duplicate means two original copies of the registration certificate).

6. **What is the process for rejection of certificate of registration?**

   As per Section 19(2) and Rule 6(3) “If after enquiry and after giving an opportunity of being heard to the applicant and having regard to the advice of the Advisory Committee, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of the Act and the rules, it shall, for reasons to be recorded in writing, reject the application for registration and communicate such rejection to the applicant as specified in Form C (enclosed as Annexure 4).

7. **What is the validity of registration?**

   As per Rule 7 of the PCPNDT Act “Every certificate of registration shall be valid for a period of five years from date of issue”. Date of issue should be five years before the exact ending date mentioned in column 1 of Form B.

8. **How does a clinic apply for renewal of registration?**

   As per Section 19(3) “Every certificate of registration shall be renewed in such manner and after such period and on payment of such fees as may be prescribed”. As per Rule 8(1) “An application for renewal of certificate of registration shall be made in duplicate in form A, to the Appropriate Authority thirty days before the date of expiry of the certificate of registration”. Process followed for renewal would be the same as that for grant of registration. Appropriate Authority will make an enquiry and if the applicant has complied with all requirements, put up an application to Advisory
Committee and either grant (Rule 8(2)) or reject (Rule 8(3)) renewal of registration in Form B/C respectively. As per Rule 8(4) “the fees payable for renewal of certificate of registration shall be one half of the fees provided for registration”.

As per Rule 8(5) on receipt of renewed certificate of registration in duplicate or on receipt of communication of rejection of application of renewal, both copies of the earlier certificate of registration shall be surrendered by the Center immediately to the Appropriate Authority”.

9. **Is certificate of registration transferable?**

   As per Rule 6(6) “The certificate of registration shall be non-transferable. In the event of change of ownership or change of management or on ceasing to function as a Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, USG or imaging centre, both copies of the certificate of registration shall be surrendered to the Appropriate Authority’.

   As per Rule 6(7) In the event of change of ownership or change of management of the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, USG or imaging centre, the new owner or manager of such centre/laboratory/ clinic shall apply afresh for grant of certificate of registration.

10. **What happens if Appropriate Authority fails to communicate grant or rejection of renewal of registration to the applicant?**

   Grant or rejection of renewal of registration shall be communicated to the applicant within a period of 70 days from receipt of application. As per Rule 18A – Code of Conduct for Appropriate Authorities (Amendment dated 24-2-2014). In the event of failure of Appropriate Authority to grant renewal of registration or to communicate rejection of renewal within a period of 70 days from date of receipt of application, it shall be deemed that registration has been renewed.
The PCPNDT Act through its various sections and rules places a duty on every Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic to be organized in a manner so as to aid implementation of the Act. This chapter highlights the key Sections/Rules to be followed by clinics to ensure compliance as per the Act.

1. How should a Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic (static or mobile) be organized so that it is PCPNDT compliant?

As per Section 19(4) of the PCPNDT Act, the certificate of registration shall be displayed by the registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic in a conspicuous place at its place of business. The same is also stated in Rule 6(2) of the Act. It is expected that one copy of the original registration certificate be displayed in the clinic in the waiting area and the other be filed along with all other papers. It is preferable to display Xerox copies of the registration certificate where ever a sonography machine is kept.

Rule 17(1) of the PCPNDT Act states that Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, USG or Imaging centre shall prominently display on its premises a notice in English and in the local language or languages for the information of the public, stating that disclosure of the sex of the foetus is prohibited under law.

Rule 17(2) states that at least one copy each of the Act and Rules shall be available on the premises of every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, USG or Imaging Centres and shall be made available to the clientele on demand for perusal.
Rule 13 of the Act states that every Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall intimate every change of employee, place, address and equipment installed to the Appropriate Authority at least 30 days in advance of the expected date of such change and seek reissuance of certificate of registration from the Appropriate Authority with the change duly incorporated (As per Amendment dated 4-6-2012).

In Maharashtra, Government has given a special Machine Registration Certificate number (MRC Number) to each machine. This number should be displayed prominently on the machine using a sticker.

2. What are the rules related to Portable machines?

As per Rule 3B (Amendment dated 7-2-2012) Portable USG machine or any other portable machine which has the potential for selection of sex before conception or detection of sex during pregnancy shall be used within the premises it is registered in for providing services to indoor patients or as part of a mobile medical unit providing a bouquet of health and medical services. Bouquet of services means a mobile health/medical unit providing curative services, reproductive and child health services, family planning services, diagnostic services and emergency services and care in times of disaster or epidemic or public health emergency or accidents, etc.

In case of a mobile medical unit, as per Rule 6(2A) Registration Certificate should be displayed inside the vehicle in a conspicuous place. The certificate should clearly specify area of operation which shall not exceed the district where it is registered, number of machines installed in the vehicle, make and model of the portable machines, registration number of vehicle and full address of service provider for the mobile medical unit.

As per Rule 6(2B) Portable USG machine used for conducting pre natal diagnostic tests shall be an integral part of the mobile medical unit and shall not be used outside the unit under any circumstances.
Rule 6(2C) states that in case of breakdown of the vehicle or for any other reason due to which the registered mobile medical unit cannot be used as a genetic clinic, the Appropriate Authority has to be informed within a period of seven days.

3. What are the qualifications for conducting sonography?

All radiologist and gynecologist with a Post Graduate degree or diploma can conduct sonography. As per circular form GOI dated 16th August 2012 (No. N 24026/52/2008-PNDT)

Rule 3(1) (b) (Amendment dated 9-1-2014) states that any Registered Medical Practitioner (RMP) who has undergone a 300 hour training titled Fundamentals in Abdomino Pelvic Ultra Sonography can conduct sonography. The syllabus for the training is specified in schedule I of the Amended Rules of the PCPNDT Act and assessment is specified in schedule II. RMPs already practicing with experience certificate or training certificate need to qualify a competency based assessment specified in schedule II on or before January 2017.

As per Rule 3(3) (Amendment dated 5-6-2012) a medical practitioner qualified under the Act to conduct ultrasonography shall be permitted to be registered with a maximum of two centers within a district. The rule also mentions that the consulting hours of such medical practitioners shall be clearly specified by each clinic/centre.
Chapter 4

MAINTENANCE OF RECORDS

The provisions of the Act envisage and emphasise the maintenance and preservation of records. Proviso to Section 4 of the Act mandates that the person conducting ultrasonography on a pregnant woman shall keep complete records thereof in the clinic in such manner as prescribed in Rule 9. Any deficiency or inaccuracy found in the maintenance of records shall amount to contravention of provision of Section 5* or 6** unless the person conducting such sonography proves to the contrary. This Chapter makes an attempt to highlight different records that need to be maintained by Genetic counselling centres, Genetic clinics and Genetic Laboratories.

1. What are the records to be maintained by a Genetic Counselling Centre, Genetic Laboratory or Genetic clinic?

As per Rule 9(1) very Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic including a mobile Genetic Clinic, USG and imaging centre shall maintain a register showing in serial order, the names and address of the men or women given genetic counselling, subjected to prenatal diagnostic procedures or prenatal diagnostic tests, the names of their spouse or father and the date on which they first reported for such counseling procedure or test. A sample copy of the register as per Rule 9(1) is enclosed as Annexure 5.

As per Rule 9(2) the record to be maintained by every Genetic counselling centre in respect of each women counseled shall be as per Form D (enclosed as Annexure 6).

Rule 9(3) of the Act states that record to be maintained by every Genetic laboratory in respect of each man or women subject to any pre natal diagnostic procedure/technique/test shall be specified in Form E (enclosed as Annexure 7).

* Written consent of pregnant women and prohibition on communicating sex of foetus.
** Determination of sex prohibited.
As per Rule 9(4) the record to be maintained by every Genetic Clinic including a mobile Genetic Clinic in respect of each man or woman subjected to any prenatal diagnostic procedure/technique/test shall be specified in Form F (enclosed as Annexure 8). In Maharashtra all F Forms need to be filled online. (As per Government resolution number ra-kra/257/ku-ka/Mantralaya Mumbai dated 24/09/2012.)

As per Rule 9 (7), In case the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, Ultra Sound Clinic or Imaging Centre maintains records on computer or other electronic equipment, a printed copy of the record shall be taken and preserved after authentication b a person responsible for such record.

Rule 9(8) states that every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres shall send a complete report in respect of all pre-conception or pregnancy related procedures/techniques/ tests conducted by them in respect of each month by 5th day of the following month to the concerned Appropriate Authority. Format for sending monthly report to Appropriate Authority is enclosed as Annexure 9.

2. For how long are the records to be kept?

Section 29(1) of the PCPNDT Act states that all records charts, forms, reports, consent letters and all other documents required to be maintained under this Act and the rules shall be preserved for a period of two years or for such period as may be prescribed. Provided that if any criminal or other proceedings are instituted against any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic the records and all other documents of such centre, laboratory or clinic shall be preserved till the final disposal of such proceedings.

Rule 9 (6) states that all case-related records, forms of consent, laboratory results, microscopic pictures, sonographic plates or slides, recommendations and letters shall be preserved by the Genetic Counselling Centre, Genetic Laboratory or
Genetic Clinic, Ultra Sound Clinic or Imaging Centre for a period of two years from
the date of completion of counselling, pre-natal diagnostic procedure or pre-natal
diagnostic test, as the case may be. In the event of any legal proceedings, the records
shall be preserved till the final disposal of legal proceedings, or till the expiry of the
said period of two years, whichever is later.

In the case, Suo moto vs State of Gujarat 2009Cri. L.J. 721 (F.B.), full bench
of Gujarat High Court was deciding the reference made by a single judge, whether
deficiency or inaccuracy in filing Form F as required under statutory provision is
merely a procedural lapse. The full bench has given progressive interpretation to
Section 4(3) of the Act holding that by virtue of deeming provision of the proviso to
said section, contravention of the provisions of Section 5 or 6 is legally to be
presumed. Hence, there need not be allegation in the complaint about the
inaccuracy or deficiency in maintaining record as resulting in contraventions of
Section 5 or 6 of the Act. Burden to prove the contravention of this provision does not
lie on the prosecution. It also stated that deficiency or inaccuracy in filling Form F
under Rule 9 is not merely a procedural lapse but an independent offence.
INSPECTION OF CENTRES

For ensuring strict compliance with the provisions of the Act, Section 30 gives full authority and power to Appropriate Authorities to enter and search any premises where they have reason to believe that a breach of any of the provisions of the Act has been or is being committed. Appropriate Authorities are further authorized under the Act to seize and seal any record, register, document, book, pamphlet, advertisement or any other material object found therein if they have a reason to believe that it may furnish evidence of the commission of an offence punishable under the Act. Rule 12 lays down the procedure for such search and seizure.

1. **Does Appropriate Authority have the power to inspect a clinic and conduct search and seizure?**

   Section 30 authorizes an Appropriate Authority to inspect a clinic, conduct search and seize records. As per this section, the Appropriate Authority or any officer authorized by Appropriate Authority in this behalf, can enter and search a clinic at all reasonable times. As per Rule 12 Appropriate Authority or any officers authorized in this behalf can enter and search a clinic in the presence of two or more independent witnesses.

2. **What all can be inspected/searched, seized by Appropriate Authority?**

   As per Section 30, the following can be inspected, seized and sealed if Appropriate Authority has reason to believe that they may furnish evidence of the commission of an offence punishable under this Act.
- Registers
- Records
- Documents
- Book
- Pamphlet
- Advertisement
- Any other material object

3. **Can the Appropriate Authority seize/seal a USG machine/imaging machine?**

A. The Appropriate Authority has the power to seize/seal the USG machine.

*In the case of Dr. Mrs. Suhasini Umesh Karanjakar Vs Kolhapur Municipal Corp. 2011(4) AIR Bom R 326 (F.B.), the full bench of High Court of Bombay made an attempt to answer whether the power to search, seize and seal any other material object conferred under section 30 of the Act includes the USG machine or any other machine or object and is the Appropriate Authority empowered to seize and seal the sonography machine which is suspected to being used for conducting sex determination. The full bench Judgment held that, words “any other material object” used in S.30 of the Act and Explanation (2) to Rule 12 clearly provide that Appropriate Authority is empowered to seize and seal ultrasound machines, other machines and equipments capable of aiding or assisting in sex-selection. (Earlier contrary view reversed).*
4. Can a machine that has been sealed by an Appropriate Authority be released during pendency of trial since it is a muddemal property and would be damaged if not used?

The machine sealed by an Appropriate Authority cannot be released during pendency of trial.

In the case of Dr. Vandana Ramchandra Patil Vs State of Maharashtra and Anr, Bombay High Court 23rd January 2013 (http://www.radbazar.com/content/images/stories/04032013.pdf), the petitioner held that the sonography Machine seized by Appropriate Authority should be released on Indemnity Bond during pendency of inquiry and trial, as it is a muddemal property which will get damaged, if unused and hence there is no point in keeping the same till conclusion of trial. The High Court held: that offences under PCPNDT Act are committed essentially with the use of Sonography Machine. The crime is essentially repetitive in nature. The prevention of crime is best achieved by sealing the Machine. If the seal is opened, the accused is facilitated to repeat the crime. Once a case is made out against the Accused, repetition of such crime has to be prevented. The accused, therefore, cannot use machine until trial is over. Order of release of machine passed mechanically like any other property lacks sensitivity. The Court must consider the impact and effect of each Order. A machine sealed cannot be directed to be re-opened or released. It should remain sealed till the conclusion of trial.
In workshops and training programs organized with owners of Genetic counselling centres, Genetic Clinics and Genetic laboratories over the last two years, a number of questions were repeatedly raised to seek clarifications. Questions most commonly asked have been compiled in this chapter.

1. Do Genetic clinics need to maintain a hard copy of F form, if it is being submitted online?

   As per Rule 9(7) a hard copy of F form needs to be maintained even if it is being submitted online. Hard copy could be F – Form manually filled in or a printout of the copy submitted online. In both cases it should have a declaration by the pregnant woman undergoing prenatal diagnostic procedure that she does not want to know the sex of the foetus and declaration by the doctor conducting the prenatal diagnostic procedure that he/she will not disclose sex of the foetus to anybody in any manner. The signature of both the client and doctor are mandatory on the hard copy. Printed copy taken online must be authenticated by the doctor concerned.

2. Should a copy of the F form be given to the pregnant women?

   As per the PCPNDT Act, there is no need to give a copy of Form F to the pregnant women. However if a pregnant woman demands a copy of the F form it can be given.

3. In which language should USG clinics keep a copy of PCPNDT Act?

   Rule 17(2) only states that a copy of the Act and Rules should be available on the premises. A copy of the Act in English can be kept. It would be preferable to keep a copy of the Act in the local language to be made available to clientele on demand for perusal.
4. **What is the procedure for demonstration of a USG machine?**

There is no provision in the Act regarding demonstration of a USG machine, however, MOHFW, Government of India via GR dated 14th May 2015 (No.V.11011/05/2013-PNDT). has provided clarification for procedures to followed in case of short term demonstration / display of ultrasound/ imaging machines. For display in a scientific exhibition, the organizing body should take permission form the District Appropriate Authority (DAA) specifying the details of the machine. DAA should ensure that these machines are not used for live demonstration and the organizing body has to take all responsibilities for any violation under the PCPNDT Act.

For live demonstration at workshops and conferences, permission should be granted only when these machines are demonstrated in registered facilities under the PCPNDT Act, with transmission facility for viewing by the delegates. Along with the request by the organizing body the details of the equipment used in the workshops/conferences and list of experts/professionals demonstrating the machines along with qualifications must be submitted. The registered facility that provides its premises for same should also intimate to their respective District Appropriate Authority all information pertaining to equipment used and experts/ professional demonstrating the technology. In all live demonstrations and conferences, Appropriate Authority should ensure that all records under the provisions of the PCPNDT Act are maintained and preserved.

5. **What is self referral?**

Self referral means a doctor’s self prescription (If the doctor feels that a USG is indicated, such a note must be written on one’s own letter head). It does not mean a client coming to clinic and requesting for a test or relatives requesting for test of a pregnant woman.
6. **What is a referral slip? What all should a referral slip contain?**

   Referral slip should be on the letter head of the referring doctor and not on the letter head of the imaging centre. It should contain signature of the referring doctor. A sample referral slip is enclosed as **Annexure 10**.

7. **Can a clinic owner demand for a copy of the inspection report carried out by the Appropriate Authority?**

   Yes, as per Rule 18A(8)(1) Code of Conduct for Appropriate Authorities (Amendment dated 24-2-2014) a copy of the inspection report should be given to the clinic owner.

8. **When can an Appropriate Authority conduct enquiry / inspection of a USG clinic for grant/renewal of registration?**

   As per Rule 6(4) inspection at the premises of a USG clinic for grant/renewal of registration shall be carried out only after due notice is given to the applicant by the Appropriate Authority.

9. **As per Rule 17(1) all USG clinics are supposed to display a board stating that disclosure of sex of foetus is prohibited under the law - Does the board have to be of a particular size, shape and colour?**

   No there is no specific size, shape or colour specified under the PCPNDT Act, but the board should be readable and should be displayed at a prominent place in the clinic.

10. **If a USG centre has more than one imaging machine what is the registration fee?**

    As per Rule 5, registration fee is for the centre and not for a machine. If a centre has more than one imaging machine the fee would still be Rs.25,000/-. However, if a
centre provides a combination of services under Genetic Counselling Centre, Genetic Clinic or Genetic Laboratory the Fee would be Rs.35,000/-.

11. If registration of a USG centre has been rejected can the applicant reapply?
   The applicant can reapply for registration if all reasons noted by Appropriate Authority for rejection of registration are complied by the applicant. The Act is silent about duration between rejection of registration and reapplication.

12. If there is a change in place, equipment, person does a clinic owner have to pay registration fee again?
   No, there is no need to pay registration fee incase of change in place, equipment or person.

13. Can a non medical person open a sonography clinic?
   Yes, a non medical person can be an owner of a sonography clinic but cannot conduct sonography.

14. What is minimum space for a USG room?
   Minimum space for USG room is not specified in Act. But it should have sufficient space, to accommodate USG machine, its monitor and other attachments, examination table/cot for patient, Doctor’s chair and space for female attendant, without overcrowding.
ANNEXURES
ANNEXURE 1 - FORM A*

[See rules 4(1) and 8(1)]

(To be submitted in Duplicate with supporting documents as enclosures)

FORM OF APPLICATION FOR REGISTRATION OR RENEWAL OF REGISTRATION OF A GENETIC COUNSELLING CENTRE/GENETIC LABORATORY/GENETIC CLINIC/ULTRASOUND CLINIC/IMAGING CENTRE

1. Name of the applicant
   (Indicate name of the organization sought to be registered)

2. Address of the applicant

3. Type of facility to be registered
   (Please specify whether the application is for registration of a Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre or any combination of these)

4. Full name and addressAddresses of Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/ Ultrasound Clinic/Imaging Centre with Telephone/Fax number(s)/Telegonic/Telex/E-mail address (s).

5. Type of ownership of Organisation (individual ownership/partnership/company/co-operative/any other to be specified). In case type of organization is other than individual ownership, furnish copy of articles of association and names and addresses of other persons responsible for management, as enclosure.

6. Type of Institution (Govt. Hospital/Municipal Hospital/Public Hospital/Private Hospital/Private Nursing Home/Private clinic/Private laboratory/any other to be stated)

7. Specific pre-natal diagnostic procedures/tests for which approval is sought
   (a) Invasive (i) amniocentesis/chorionic villi aspiration/chromosomal/biochemical/molecular studies
   (b) Non-Invasive Ultrasonography

   Leave blank if registration is sought for Genetic Counselling Centre only.

8. Equipment available with the make and model of each equipment (List to be attached on a separate sheet).

9.  (a) Facilities available in the Counselling Centre.
    (b) Whether facilities are or would be available in the Laboratory/Clinic for the following tests:
        (i) Ultrasound
        (ii) Amniocentesis
        (iii) Chorionic villi aspiration
        (iv) Foetoscopy
        (v) Foetal biopsy
        (vi) Cordocentesis

    Whether facilities are available in the Laboratory/ Clinic for the following:
        (i) Chromosomal studies
        (ii) Biochemical studies
        (iii) Molecular studies
        (iv) Preimplantation genetic diagnosis

10. Names, qualifications, experience and registration number of employees (may be furnished as an enclosure).

11. State whether the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/ultrasound clinic/imaging centre* qualifies for registration in terms of requirement laid down in Rule 3.

12. For renewal applications only:
    (a) Registration No.
    (b) Date of issue and date of expiry of existing certificate of registration.

13. List of Enclosures:

    (Please attach a list of enclosures / supporting documents attached to this application.)
Date:
Place

.................................................................

Name, designation and signature of the person authorized to
sign on behalf of the organisation to be registered.

DECLARATION

I, Sh./Smt./Kum./Dr............................................................
son/daughter/wife of ...................... aged ................. years resident
................................................................. working as (indicate designation)
................................................................. in (indicate name of the organisation to be
registered) ........................................................... hereby declare that I have read and
understood the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act,
1994 (57 of 1994) and the Pre-natal Diagnostic Techniques (Regulation and Prevention of
Misuse) Rules, 1996,

I also undertake to explain the said Act and Rules to all employees of the Genetic
Counselling Centre / Genetic Laboratory/Genetic Clinic/ultrasound clinic/imaging centre in
respect of which registration is sought and to ensure that Act and Rules are fully complied
with.

Date:
Place

.................................................................

Name, designation and signature of the person authorized to
sign on behalf of the organisation to be registered

[SEAL OF THE ORGANISATION SOUGHT TO BE REGISTERED]
ACKNOWLEDGEMENT

[See Rules 4(2) and 8(1)]

The application in Form A in duplicate for grant*/renewal* of registration of Genetic Counselling Centre* / Genetic Laboratory* / Genetic Clinic* / Ultrasound Clinic* /Imaging Centre* by ........................................ (Name and address of applicant) has been received by the Appropriate Authority .................. On (date).

* The list of enclosures attached to the application in Form A has been verified with the enclosures submitted and found to be correct.

OR

*On verification it is found that the following documents mentioned in the list of enclosures are not actually enclosed.

This acknowledgement does not confer any rights on the applicant for grant or renewal of registration.

..................................................................................................
Signature and Designation of Appropriate Authority, or authorized person in the Office of the Appropriate Authority.

Date:

Place:

SEAL

ORIGINAL/DUPLICATE FOR DISPLAY**
ANNEXURE 2 - AFFIDAVIT CUM UNDERTAKING
(Sample)

I, Dr. Shri/Smt __________________________, _________ Age ____,
Son/daughter/wife of __________________________ residing at
(Full address) ___________________________________________
__________________________________ do hereby solemnly affirm oath as:

I, hereby say and undertake that the Genetic Counselling Centre*, Genetic Laboratory*/ Genetic Clinic* combination thereof as the case may be, shall not conduct any test or procedures, by what-so-ever name called, for selection of “Sex” before or after conception or for detection of sex of foetus except for diseases specified in Section 4(2) nor shall the sex or foetus be disclosed to anybody.

I also undertake to explain the said Act and Rules to all employees of my Ultrasound Centre / Genetic Laboratory / Genetic Clinic / Genetic Counselling Centre in respect of which registration is sought and to ensure that Act Rules are fully complied with. I also undertake to display prominently at my Ultrasound Centre / Genetic Clinic / Genetic Laboratory / Genetic Counselling Centre, combination thereof as the case may be, a notice that we do not conduct any technique test, procedure, etc by whatever name called for detection of sex of foetus or for selection of sex before or after conception.

This Affidavit is made for submitting the same to the Appropriate Authority along with an application for Registration of Genetic Clinic / Genetic Laboratory / Genetic Counselling Centre/ ultrasound clinic or combination thereof (as the case may be).

I hereby declare that I have read and understood the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994) and the Pre-natal Diagnostic Techniques (Regulations and Prevention of Misuse) Rules 1996 and Amendment 2003.

* Strike out whichever is not applicable.
The above noted contents are true and correct to the best of my knowledge and if found false, I may be liable for punishment under section 199, 200, 193(2) of Indian Penal Court.

.............................................................

Signature
Name of deponent
Seal/Stamp of the deponent/organization
sought to be registered
ANNEXURE 3 - FORM B

[(See Rules 6(2), 6(5) and 8(2)]

CERTIFICATE OF REGISTRATION
(To be issued in duplicate)

1. In exercise of the powers conferred under Section 19 (1) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994), the Appropriate Authority ................. hereby grants registration to the Genetic Counselling Centre*/ Genetic Laboratory*/ Genetic Clinic*/ Ultrasound Clinic*/Imaging Centre* named below for purposes of carrying out Genetic Counselling/Pre-natal Diagnostic Procedures/Pre-natal Diagnostic Tests/ultrasonography* under the aforesaid Act for a period of five years ending on ...............

2. This registration is granted subject to the aforesaid Act and Rules thereunder and any contravention thereof shall result in suspension or cancellation of this Certificate of Registration before the expiry of the said period of five years apart from prosecution.

A. Name and address of the Genetic Counselling Centre*/ Genetic Laboratory*/ Genetic Clinic*/ Ultrasound Clinic*/ Imaging Centre*.

B. Pre-natal diagnostic procedures* approved for (Genetic Clinic).

   *Non-Invasive*

   (i) Ultrasound

   *Invasive*

   (ii) Amniocentesis

   (iii) Chorionic villi biopsy

   (iv) Foetoscopy

   (v) Foetal skin or organ biopsy

   (vi) Cordocentesis

   (vii) Any other (specify)

* Strike out whichever is not applicable or necessary
C. Pre-natal diagnostic tests* approved (for Genetic Laboratory)
   (i) Chromosomal studies
   (ii) Biochemical studies
   (iii) Molecular studies

D. Any other purpose (please specify)

3. Model and make of equipments being used (any change is to be intimated to the
   Appropriate Authority under rule 13).

4. Registration No. allotted

5. Period of validity of earlier Certificate of Registration.
   (For renewed Certificate of Registration only)  From .......... To ........

.................................................................

Signature, name and designation of

The Appropriate Authority

SEAL

Date:
ANNEXURE 4 - FORM C

[See Rules 6(3), 6(5) and 8(3)]

FORM FOR REJECTION OF APPLICATION
FOR GRANT/RENEWAL OF REGISTRATION

In exercise of the powers conferred under Section 19(2) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994, the Appropriate Authority ........................................ hereby rejects the application for grant*/renewal* of registration of the undermentioned Genetic Counselling Centre*/Genetic Laboratory*/ Genetic Clinic*/ Ultrasound Clinic*/ Imaging Centre*.

(1) Name and address of the Genetic Counselling Centre*/Genetic Laboratory*/ Genetic Clinic*/ Ultrasound Clinic*/ Imaging Centre*

(2) Reasons for rejection of application for grant/renewal of registration:

..................................................................................................................

Signature, name and designation of the Appropriate Authority with SEAL of Office

Date:

Place:

* Strike out whichever is not applicable or necessary
ANNEXURE 5 – REGISTER OF CLIENTS SUBJECTED TO PRE-NATAL DIAGNOSTIC PROCEDURE/TESTS AS PER RULE 9(1)

<table>
<thead>
<tr>
<th>Sr.No.</th>
<th>Name of Women/Men Undergoing test</th>
<th>Address and Contact no.</th>
<th>Name of Spouse or Father</th>
<th>Date of diagnostic test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
ANNEXURE 6 - FORM D

[See rule 9(2)]

FORM FOR MAINTENANCE OF RECORDS
BY THE GENETIC COUNSELLING CENTRE

1. Name and address of Genetic Counselling centre.
2. Registration No.
3. Patient’s name
4. Age
5. Husband’s/Father’s name
6. Full address with Tel. No., if any
7. Referred by Full name and address of Doctor(s) with registration No.(s) (Referral
   note to be preserved carefully with case papers)
8. Last menstrual period/weeks of pregnancy
9. History of genetic/medical disease in the family (specify)

Basis of diagnosis:
   (a) Clinical
   (b) Bio-chemical
   (c) Cytogenetic
   (d) Other (e.g. radiological, ultrasonography)

10. Indication for pre-natal diagnosis
A. Previous child/children with:
   (i) Chromosomal disorders
   (ii) Metabolic disorders
   (iii) Congenital anomaly
   (iv) Mental retardation
   (v) Haemoglobinopathy
(vi) Sex linked disorders
(vii) Single gene disorder
(viii) Any other (specify)

B. Advanced maternal age (35 years or above)
C. Mother/father/sibling having genetic disease (specify)
D. Others (specify)

11. Procedure advised*
   (i) Ultrasound
   (ii) Amniocentesis
   (iii) Chorionic villi biopsy
   (iv) Foetoscopy
   (v) Foetal skin or organ biopsy
   (vi) Cordocentesis
   (vii) Any other (specify)

12. Laboratory tests to be carried out
   (i) Chromosomal studies
   (ii) Biochemical studies
   (iii) Molecular studies
   (iv) Preimplantation genetic diagnosis

13. Result of diagnosis
    If abnormal give details. Normal / Abnormal

14. Was MTP advised?

15. Name and address of Genetic Clinic to which patient is referred.

16. Dates of commencement and completion of genetic counseling.

........................................................................................................

Name, Signature and Registration No. of the
Medical Geneticist/Gynaecologist/Paediatrician

Place: administering Genetic Counselling.

Date:
ANNEXURE 7 - FORM E

[See Rule 9(3)]

FORM FOR MAINTENANCE OF RECORDS BY GENETIC LABORATORY

1. Name and address of Genetic Laboratory
2. Registration No
3. Patient’s name
4. Age
5. Husband’s/Father’s name
6. Full address with Tel. No., if any
7. Referred by/sample sent by (full name and address of Genetic Clinic) (Referral note to be preserved carefully with case papers)
8. Type of sample: Maternal blood/Chorionic villus sample/amniotic fluid/Foetal blood or other foetal tissue (specify)
9. Specify indication for pre-natal diagnosis

A. Previous child/children with
   (i) Chromosomal disorders
   (ii) Metabolic disorders
   (iii) Malformation(s)
   (iv) Mental retardation
   (v) Hereditary haemolytic anaemia
   (vi) Sex linked disorder
   (vii) Single gene disorder
   (viii) Any other (specify)

B. Advanced maternal age (35 years or above)

C. Mother/father/child/parent having genetic disease (specify)

D. Other (specify)
10. Laboratory tests carried out (give details)
   (I) Chromosomal studies
   (ii) Biochemical studies
   (iii) Molecular studies
   (iv) Preimplantation genetic diagnosis
11. Result of diagnosis
    If abnormal give details. Normal/Abnormal
12. Date(s) on which tests carried out.
    The results of the Pre-natal diagnostic tests were conveyed to ................. on
    .........................

........................................................................
Name, Signature and Registration No. of the
Medical Geneticist/Director of the Institute

Place:

Date:
ANNEXURE 8 - FORM F*

[See proviso to section 4(3), rule 9(4) and rule 10(1-A)]

FORM FOR MAINTENANCE OF RECORD IN CASE OF PRENATAL DIAGNOSTIC TEST /PROCEDURE BY GENETIC CLINIC/ULTRASOUND CLINIC/IMAGING CENTRE

Section A: To be filled in for all Diagnostic Procedures/Tests
1. Name and complete address of Genetic Clinic/Ultrasound Clinic/Imaging centre

2. Registration No. (Under PC & PNDT Act, 1994)

3. Patient’s name Age

4. Total Number of living children
   (a) Number of living Sons with age of each living son (in years or months):
   (b) Number of living Daughters with age of each living daughter (in years or months):

5. Husband’s /Wife’s/ Father’s / Mother’s Name

6. Full postal address of the patient with Contact Number, if any

7. (a) Referred by (Full name and address of Doctor(s)/ Genetic Counselling Centre)

(Referral slips to be preserved carefully with Form F)

* Substituted by G.S.R.77(E), dated 31-1-2014 (w.e.f. 31-1-2014)
(b) Self-Referral by Gynaecologist/Radiologist/Registered Medical Practitioner conducting the diagnostic procedures ...........................................................

..........................................................................................................................................................................................

(Referral note with indications and case papers of the patient to be preserved with Form F)

(Self-referral does not mean a client coming to a clinic and requesting for the test or the relative/s requesting for the test of a pregnant woman)

8. Last menstrual period or weeks of pregnancy.................................................................

Section B: To be filled in for performing non-invasive diagnostic Procedures/Tests only

9. Name of the doctor performing the procedure/s...........................................................

10. Indication/s for diagnosis procedure............................................................................

(specify with reference to the request made in the referral slip or in a self-referral note)

(Ultrasonography prenatal diagnosis during pregnancy should only be performed when indicated. The following is the representative list of indications for ultrasound during pregnancy. (Put a “Tick” against the appropriate indication/s for ultrasound)

(i) To diagnose intra-uterine and/or ectopic pregnancy and confirm viability.

(ii) Estimation of gestational age (dating).

(iii) Detection of number of fetuses and their chorionicity.

(iv) Suspected pregnancy with IUCD in situ or suspected pregnancy following contraceptive failure/MTP failure.

(v) Vaginal bleeding/leaking.

(vi) Follow-up of cases of abortion.

(vii) Assessment of cervical canal and diameter of internal os.

(viii) Discrepancy between uterine size and period of amenorrhea.

(ix) Any suspected adenexal or uterine pathology/abnormality.

(x) Detection of chromosomal abnormalities, fetal structural defects and other abnormalities and their follow-up.
(xi) To evaluate fetal presentation and position.
(xii) Assessment of liquor amnii.
(xiii) Pre-term labor / pre-term premature rupture of membranes.
(xiv) Evaluation of placental position, thickness, grading and abnormalities (placenta praevia, retro placental hemorrhage, abnormal adherence etc.).
(xv) Evaluation of umbilical cord – presentation, insertion, nuchal encirclement, number of vessels and presence of true knot.
(xvi) Evaluation of previous Caesarean Section scars.
(xvii) Evaluation of fetal growth parameters, fetal weight and fetal well being.
(xviii) Color flow mapping and duplex Doppler studies.
(xix) Ultrasound guided procedures such as medical termination of pregnancy, external cephalic version etc. and their follow-up.
(xx) Adjunct to diagnostic and therapeutic invasive interventions such as chorionic villus sampling (CVS), amniocenteses, fetal blood sampling, fetal skin biopsy, amnio-infusion, intrauterine infusion, placement of shunts, etc.
(xxi) Observation of intra-partum events.
(xxii) Medical/surgical conditions complicating pregnancy.
(xxiii) Research/scientific studies in recognized institutions.

11. Procedures carried out (Non-Invasive) (Put a “Tick” on the appropriate procedure)
   (i) Ultrasound
      *(Important Note.— Ultrasound is not indicated/advised/performed to determine the sex of fetus except for diagnosis of sex-linked diseases such as Duchene Muscular Dystrophy, Hemophilia A & B etc.)*
   (ii) Any other (specify) ..............................

12. Date on which declaration of pregnant woman/person was obtained ......................
13. Date on which procedures carried out ........................................................................
14. Result of the non-invasive procedure carried out (report in brief of the test including ultrasound carried out) ........................................................................
15. The result of pre-natal diagnostic procedures was conveyed to...............on........

16. Any indication for MTP as per the abnormality detected in the diagnostic procedures/tests.................................................

Date: ..................................................................................................

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

Name, Signature and Registration Number with Seal of the Gynaecologist/Radiologist/Registered Medical Practitioner performing Diagnostic Procedure/s

Section C: To be filled for performing invasive Procedures/Tests only

17. Name of the doctor/s performing the procedure/s..........................................................

18. History of genetic/medical disease in the family (specify) ..................................................

   Basis of diagnosis (“Tick” on appropriate basis of diagnosis):

   (a) Clinical    (b) Bio-chemical

   (c) Cytogenetic (d) other (e.g., radiological, ultrasonography etc.-specify)

19. Indication/s for the diagnosis procedure (“Tick” on appropriate indication/s):

A. Previous child/children with:

   (i) Chromosomal disorders  (ii) Metabolic disorders
   (iii) Congenital anomaly    (iv) Mental Disability
   (v) Haemoglobinopathy      (vi) Sex linked disorders
   (vii) Single gene disorder  (viii) Any other (specify)

B. Advanced maternal age (35 years)

C. Mother/father/sibling has genetic disease (specify)

D. Other (Specify) .................................................................

20. Date on which consent of pregnant woman / person was obtained in Form G prescribed in PC&PNDT Act,1994 .................................................................
21. Invasive procedures carried out (“Tick” on appropriate indication/s)
   (i) Amniocentesis  (ii) Chorionic Villi aspiration
   (iii) Fetal biopsy  (iv) Cordocentesis
   (v) Any other (specify)

22. Any complication/s of invasive procedure (specify) ..............................................

23. Additional tests recommended (Please mention if applicable)
   (i) Chromosomal studies  (ii) Biochemical studies
   (iii) Molecular studies  (iv) Pre-implantation gender diagnosis
   (v) Any other (specify)

24. Result of the Procedures/Tests carried out (report in brief of the invasive tests
procedures carried out) ........................................................................................................

25. Date on which procedures carried out ...........................................................................

26. The result of pre-natal diagnostic procedures was conveyed to .................. on ............

27. Any indication for MTP as per the abnormality detected in the diagnostic
procedures/ tests ..................................................................................................................

Date:

Place:

..........................................................................................................................

Name, Signature and Registration Number
with Seal of the Place Gynaecologist/Radiologist/
Registered Medical Practitioner performing
Diagnostic Procedure/s
Section D: Declaration

DECLARATION OF THE PERSON UNDERGOING
PRENATAL DIAGNOSTIC TEST/PROCEDURE

I, Mrs./Mr.__________________________________________________________ declare that by undergoing........................................Prenatal Diagnostic Test/Procedure.
I do not want to know the sex of my foetus.
Date: 
Place: ............................................................................................

Signature/Thump impression of the person undergoing the
Prenatal Diagnostic Test/Procedure

In Case of thumb Impression:

Identified by (Name) ..........................................................Age............Sex........
Relation (if any)..........................Address & Contact No.................................

Signature of a person attesting thumb impression.................Date............

DECLARATION OF DOCTOR/PERSON CONDUCTING
PRE NATAAL DIAGNOSTIC PROCEDURE/TEST

I,.................................................................(name of the person conducting
ultrasonography/image scanning) declare that while conducting ultrasonography/image scanning on Ms./Mr.................................................................(name of the pregnant woman or the person undergoing pre natal diagnostic procedure/test), I have neither detected nor disclosed the sex of her fetus to anybody in any manner.

.................................................................

Signature

Date: 
Place: .................................................................

Name in Capitals, Registration Number
with Seal of the Gynaecologist / Radiologist/
Registered Medical Practitioner Conducting
Diagnostic procedure]
FORM G
[See Rule 10]
FORM OF CONSENT
(For invasive techniques)

I, ........................................... wife/daughter of ......................................... Age ........... years residing at ....................................................... hereby state that I have been explained fully the probable side effects and after effects of the pre-natal diagnostic procedures.

I wish to undergo the preimplantation/pre-natal diagnostic technique/test/procedures in my own interest to find out the possibility of any abnormality (i.e. disease/deformity/disorder) in the child I am carrying.

I undertake not to terminate the pregnancy if the pre-natal procedure/technique/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 the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994) and rules framed thereunder.

.................................................................
Date

Signature of the pregnant woman.

Place

I have explained the contents of the above to the patient and her companion (Name ........................................... Address ......................................... Relationship ......................) in a language she/they understand.

.................................................................
Name, Signature and/Registration number of Gynaecologist/Medical Geneticist/Radiologist/Paediatrician/
Director of the Clinic/Centre/Laboratory

Date

.................................................................
Name, Address and Registration number of Genetic Clinic/Institute SEAL
ANNEXURE 9 – MONTHLY REPORT FORMAT FOR GENETIC COUNSELLING CENTRE / LABORATORY / ULTRASOUND CLINIC / IMAGING CENTER / COMBINED

Name of the Genetic Counselling Centre/ Laboratory/ Ultrasound Clinic / Imaging Centre

__________________________________________________________

Registration No. : ____________________________

Name of Director / Doctor :

__________________________________________________________

Month: _________________, Year 20__

1. Total No. of Patients:

<table>
<thead>
<tr>
<th>From Maharashtra</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>From other States</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
</tr>
</tbody>
</table>

2. Issue wise Breakup of the patients:

<table>
<thead>
<tr>
<th>0 issue</th>
<th>Only 1 Male</th>
<th>Only 1 Female</th>
<th>2 or 2 + Males</th>
<th>2 or 2 + Females</th>
<th>Others</th>
</tr>
</thead>
</table>

3. Age wise Breakup of the patients:

<table>
<thead>
<tr>
<th>Less than 18 years</th>
<th>18-30 years</th>
<th>30-35 years</th>
<th>Above 35 years</th>
</tr>
</thead>
</table>
4. Duration of Pregnancy:

<table>
<thead>
<tr>
<th>Duration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 12 weeks</td>
<td></td>
</tr>
<tr>
<td>12-24 weeks</td>
<td></td>
</tr>
<tr>
<td>More than 24 weeks</td>
<td></td>
</tr>
</tbody>
</table>

5. Indication for prenatal diagnosis test/procedure:

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Type of Indication</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Previous Child with</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Chromosomal disorders</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Metabolic disorders</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Congenital anomaly</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Mental retardation</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Haemoglobinopathy</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Sex linked disorders</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Malformation (Specify)</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Hereditary hemolytic anemia</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Any other</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>Advance Maternal Age</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>Genetic Disease in Father/Mother/Sibling</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>Other (Specify)</td>
<td></td>
</tr>
</tbody>
</table>

6. Procedure advised/carried out:

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Type of Procedure / Test</th>
<th>Number Advised</th>
<th>Number Carried out</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Non - invasive</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ultrasound</td>
<td></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>Invasive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a)</td>
<td>Amniocentesis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b)</td>
<td>Chorionic Villi Biopsy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c)</td>
<td>Foetoscopy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d)</td>
<td>Foetal skin or organ biopsy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e)</td>
<td>Cordocentesis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>f)</td>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
7. Results of Prenatal Diagnosis test/procedure:

<table>
<thead>
<tr>
<th>Normal</th>
<th>Abnormal</th>
<th>Total</th>
</tr>
</thead>
</table>

8. MTP: Advised / done

<table>
<thead>
<tr>
<th>Advised / done</th>
<th>Before 12 weeks</th>
<th>After 12 weeks</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Number advised</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Number done</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature
Name of the Genetic Counselling Centre/Clinic/ Lab. Incharge:
Address:

Phone Number:

E-mail address:
ANNEXURE 10 – REFERRAL SLIP / SELF REFERRAL SLIP

(Sample)

Date: ________________

Name of doctor & address of the USG

centre to whom patient is referral : __________________________________________

A) Patient’s details:

a) Name : __________________________________________

b) Detail Address (Permanent) : __________________________________________

  __________________________________________

  __________________________________________

c) Detail Address (Temporary) : __________________________________________

d) Mobile no./ Contact no. : __________________________________________

e) No. of living children : Male - _________, Female - _________

B) Clinical findings : __________________________________________

  __________________________________________

  __________________________________________

C) Indication (s) for conducting USG : __________________________________________

  __________________________________________

  __________________________________________
D) Referring doctor’s details:

a) Name : ____________________________

b) Qualification : ____________________________

c) Registration no. : ____________________________

d) Name of Clinic / Hospital : ____________________________

e) Detail address of Clinic / Hospital : ____________________________

f) Mobile no. / Contact no. : ____________________________

g) Signature : ____________________________

h) Rubber Stamp : ____________________________