

**PRE- CONCEPTION  
AND PRE-NATAL  
DIAGNOSTIC TECHNIQUE**

**THE PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES  
(PROHIBITION OF SEX SELECTION) ACT, 1994**

**[Act, No. 57 of 1994]**

**[ 20 th September, 1994 ]**

**PREAMBLE**

*<sup>1</sup>[An Act to provide for the prohibition of sex selection, before or after conception, and for regulation of pre-natal diagnostic techniques for the purposes of detecting genetic abnormalities or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex-linked disorders and for the prevention of their misuse for sex determination leading to female foeticide and for matters connected therewith or incidental thereto.]*

Be it enacted by Parliament in the Forty-fifth Year of the Republic of India as follows:—

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**1 . Substituted b y Act 14 of 2003 , sec. 2 , for the long title (see Annexe).**

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**Section 1 - Short title, extent and commencement**

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( 1 ) This Act may be called<sup>1</sup>[the Preconception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994].

( 2 ) It shall extend to the whole of India except the State of Jammu and Kashmir.

( 3 ) It shall come into force on such date<sup>2</sup>as the Central Government may, by notification in the Official Gazette, appoint.

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**1. Substituted b y Act 14 of 2003 , sec. 3 , for "the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse)".**

**2 . Came into force on 1 - 1 - 1996 , vide G.S.R. 706 , dated 20 th December, 1995 , published in the Gazette of India, Extra., Pt. II, Sec. 3 (ii), dated 21 st December, 1995.**

**Section 2 - Definitions**

In this Act, unless the context otherwise requires,--

(bb)"embryo" means a developing human organism after fertilisation till the end of eight weeks (fifty-six days);

(be)"foetus" means a human organism during the period of its development beginning on the fifty-seventh day following fertilisation or creation (excluding any time in which its development has been suspended) and ending at the birth;]

(c)"Genetic Counselling Centre" means an institute, hospital, nursing home or any place, by whatever name called, which provides for genetic counselling to patients;

(d)"Genetic Clinic" means a clinic, institute, hospital, nursing home or any place, by whatever name called, which is used for conducting prenatal diagnostic procedures;

<sup>1</sup> [Explanation.--For the purposes of this clause, "Genetic Clinic" includes a vehicle, where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used;]

(e)"Genetic Laboratory" means a laboratory and includes a place where facilities are provided for conducting analysis or tests of samples received from Genetic Clinic for pre-natal diagnostic test;

<sup>1</sup> [Explanation.--For the purposes of this clause, "Genetic Laboratory" includes a place where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used;]

(f)"gynaecologist" means a person who possesses a post-graduate qualification in gynaecology and obstetrics;

<sup>2</sup> [(g) "medical geneticist" includes a person who possesses a degree or diploma in genetics science in the fields of sex selection and pre-natal diagnostic techniques or has experience of not less than two years in any of these fields after obtaining--

(i) any one of the medical qualifications recognised under the Indian Medical Council Act, 1956 (102 of 1956); "medical practitioner" means a medical practitioner who possesses any recognised medical qualification as defined in clause (h) of section 2 of the Indian Medical Council Act, 1956 (102 of 1956), and whose name has been entered in a State Medical Register;

<sup>1</sup> [(o)] "sex selection" includes any procedure, technique, test or administration or prescription or provision of anything for the purpose of ensuring or increasing the probability that an embryo will be of a particular sex;

(p) "sonologist or imaging specialist" means a person who possesses any one of the medical qualifications recognised under the Indian Medical Council Act, 1956 (102 of 1956) or who possesses a post-graduate qualification in ultrasonography or imaging techniques or radiology;

(q) "State Board" means a State Supervisory Board or a Union territory Supervisory Board constituted under section 16A;

2. Substituted by Act 14 of 2003, sec. 4, for clause (g) (see Annex).

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### **Section 3 - Regulation of Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics**

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On and from the commencement of this Act,—

(1) no Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic unless registered under this Act, shall conduct or associate with, or help in, conducting activities relating to pre-natal diagnostic techniques;

3[(2) no Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic shall employ or cause to be employed or take services of any person, whether on honorary basis or on payment who does not possess the qualifications as may be prescribed;]

(3) no medical geneticist, gynaecologist, paediatrician registered medical practitioner or any other person shall conduct or cause to be conducted or aid in conducting by himself or through any other person, any prenatal diagnostic techniques at a place other than a place registered under this Act.

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1. Substituted by Act 14 of 2003, sec. 5, for clause (2) (see Annex).

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### **Section 3A - Prohibition of sex-selection**

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#### **3A. Prohibition of sex-selection**

No person, including a specialist or a team of specialists in the field of infertility, shall conduct or cause to be conducted or aid in conducting by himself or by any other person, sex selection on a woman or a man or on both or on any tissue, embryo, conceptus, fluid or gametes derived from either or both of them.

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1. Inserted by Act 14 of 2003 , sec. 6 .

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### **Section 3B - Prohibition on sale of ultrasound machine, etc., to persons, laboratories, clinics, etc., not registered under the Act**

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No person shall sell any ultrasound machine or imaging machine or scanner or any other equipment capable of detecting sex of foetus to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic or any other person not registered under the Act.]

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### **Section 4 - Regulation of pre-natal diagnostic techniques**

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On and from the commencement of this Act,--

(1) no place including a registered Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic shall be used or caused to be used by any person for conducting pre-natal diagnostic techniques except for the purposes specified in clause (2) and after satisfying any of the conditions specified in clause (3);

(i) age of the pregnant woman is above thirty-five years;

(ii) the pregnant woman has undergone two or more spontaneous abortions or foetal loss;

(iii) the pregnant woman had been exposed to potentially teratogenic agents such as drugs, radiation, infection or chemicals;

(v) any other condition as may be specified by the Board;

(4) no person including a relative or husband of the pregnant woman shall ~~see or~~ encourage the conduct of any pre-natal diagnostic techniques on her except for the purposes specified in clause (2);

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1. Substituted by Act 14 of 2003, sec. 7, for clauses (3) and (4) (see Annex).

(i) eminent social scientists and legal experts;

(ii) eminent women activists from non-governmental organisations or otherwise;

(iii) eminent gynaecologists and obstetricians or experts of stri-roga or prasuti-tantra;

(iv) eminent paediatricians or medical geneticists;

(6) If a member of the Legislative Assembly or member of the Legislative Council who is a member of the State Board, becomes Minister or Speaker or Deputy Speaker of the Legislative Assembly or Chairperson or Deputy Chairperson of the Legislative Council, he shall cease to be a member of the State Board.

(7) One-third of the total number of members of the State Board shall constitute the quorum.

(8) The State Board may co-opt a member as and when required, provided that the number of co-opted members does not exceed one-third of the total strength of the State Board.

(10) In respect of matters not specified in this section, the State Board shall follow procedures and conditions as are applicable to the Board.]

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**Section 17 - Appropriate Authority and Advisory Committee**

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(1) The Central Government shall appoint, by notification in the Official Gazette, one or more Appropriate Authorities for each of the Union territories for the purposes of this Act.

Provided further that any vacancy occurring therein shall be filled within three months of the occurrence;]

(b) when appointed for any part of the State or the Union territory, of such other rank as the State Government or the Central Government, as the case may be, may deem fit.

<sup>2</sup> [(e) to take appropriate legal action against the use of any sex selection technique by any person at any place, suo motu or brought to its notice and also to initiate independent investigations in such matter;

(f) to create public awareness against the practice of sex selection or pre-natal determination of sex;

(g) to supervise the implementation of the provisions of the Act and rules;

(h) to recommend to the Board and State Boards modifications required in the rules in accordance with changes in technology or social conditions;

<sup>3</sup> [(7) No person who has been associated with the use or promotion of pre-natal diagnostic techniques for determination of sex or sex selection shall be appointed as a member of the Advisory Committee.]

Provided that the period intervening between any two meetings shall not exceed the prescribed period.

2. Inserted by Act 14 of 2003, sec: 15.

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1. Substituted by Act 14 of 2003, sec. 18, for section 22 (see Annex).

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## Section 23 - Offences and penalties

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( 1 ) Any medical geneticist, gynaecologist, registered medical practitioner or any person who owns a Genetic Counselling Centre, a Genetic Laboratory or a Genetic Clinic or is employed in such a Centre, Laboratory or Clinic and renders his professional or technical services to or at such a Centre, Laboratory or Clinic, whether on an honorary basis or otherwise, and who contravenes any of the provisions of this Act or rules made thereunder shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to ten thousand rupees and on any subsequent conviction, with imprisonment which may extend to five years and with fine which may extend to fifty thousand rupees.

<sup>1</sup>[( 2 ) The name of the registered medical practitioner shall be reported by the Appropriate Authority to the State Medical Council concerned for taking necessary action including suspension of the registration if the charges are framed by the court and till the case is disposed of and on conviction for removal of his name from the register of the Council for a period of five years for the first offence and permanently for the subsequent offence.

( 3 ) Any person who seeks the aid of any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic or ultrasound clinic or imaging clinic or of a medical geneticist, gynaecologist, sonologist or imaging specialist or registered medical practitioner or any other person for sex selection or for conducting pre-natal diagnostic techniques on any pregnant woman for the purposes other than those specified in sub -section ( 2 ) of section 4 , he shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to fifty thousand rupees for the first offence and for any subsequent offence with imprisonment which may extend to five years and with fine which may extend to one lakh rupees.

( 4 ) For the removal of doubts, it is hereby provided, that the provisions of sub section ( 3 ) shall not apply to the woman who was compelled to undergo such diagnostic techniques or such selection.]

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1. Substituted by Act 14 of 2003 , sec. 19 , for sub -sections ( 2 ) and ( 3 ) (see Annex).

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**Section 24 - Presumption in the case of conduct of pre-natal diagnostic techniques**

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**<sup>1</sup> [24. Presumption in the case of conduct of pre-nataldiagnostic techniques.--**

Notwithstanding anything contained in the IndianEvidence Act, 1872 (1 of 1872),the court shall presume unless thecontrary is proved that the pregnant woman was compelled by her husband or any otherrelative, as the case may be, to undergo pre-nataldiagnostic technique for the purposes otherthan those specified in subsection(2) of section 4 and suchperson shall be liable forabetment of offence under sub-section(3) of section 23 and shall be punishable for the offence specified under thatsection.]

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**1.**Substituted by Act 14 of 2003,sec. 20, for section 24 (see Annex).

Providedthat no order shall be made under thissection after the expiry of a period of three years from the date ofcommencement of the Pre-natal Diagnostic Techniques (Regulation and Preventionof Misuse) Amendment Act, 2002.

**(2)Every order made under thissection shall be laid, as soon asmay be after it is made, before each House of Parliament.]**

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**1.**Inserted by Act 14 of 2003, sec. 23.

(ia) the manner in which the person conductingultrasonography on a pregnant woman shallkeep record thereof in the clinic under the proviso tosub-section (3) of section 4;]

(v) the period intervening between any two meetings of the Advisory Committee under the proviso tosub-section (8) ofsection 17;

(viii) the facilities to be provided, equipment and other standards to be maintained by the Genetic CounsellingCentre, Genetic Laboratory or Genetic Clinic under sub-section (5) ofsection 18;

(x)the manner in which and the period after which a certificate of registration shall berenewed and the fee payable for such renewal under sub-section(3)of section 19;

- (xii)the period up to which records, charts, etc., shall be preserved under sub-section(1)of section 29;
- (xiv)any other matter that is required to be, or may be, prescribed.

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1. Substituted by Act 14 of 2003, sec. 24, for clause (i) (see Annex).

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#### **Section 33 - Power to make regulations**

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The Board may, with the previous sanction of the Central Government, by notification in the Official Gazette, make regulations not inconsistent with the provisions of this Act and the rules made thereunder to provide for--

- (a) the time and place of the meetings of the Board and the procedure to be followed for the transaction of business at such meetings and the number of members which shall form the quorum under sub-section (1) of section 9;
- (b) the manner in which a person may be temporarily associated with the Board under sub-section (1) of section 11;
- (c) the method of appointment, the conditions of service and the scales of pay and allowances of the officer and other employees of the Board appointed under section 12;
- (d) generally for the efficient conduct of the affairs of the Board.

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#### **Section 34 - Rules and regulations to be laid before Parliament**

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Every rule and every regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be

without prejudice to the validity of anything previously done under that rule or regulation.

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**Annexe 1 - ANNEXE**

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**PROVISIONS OF THE PRE-NATAL DIAGNOSTIC (TECHNIQUES REGULATION AND PREVENTION OF MISUSE) ACT, 1994 (57 OF 1994) WHICH HAVE BEEN EITHER SUBSTITUTED OR OMITTED BY THE PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) AMENDMENT ACT, 2002 (14 OF 2003), AS THEY STOOD BEFORE SUBSTITUTION OR OMISSION.**

**Long Title**

An Act to provide for the regulation of the use of pre-natal diagnostic techniques for the purpose of detecting genetic or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex linked disorders and for the prevention of the misuse of such techniques for the purpose of pre-natal sex determination leading to female foeticide; and, for matters connected therewith or incidental thereto.

**Clause (g) of section 2**

(g) "medical geneticist" means a person who possesses a degree or diploma or certificate in medical genetics in the field of pre-natal diagnostic techniques or has experience of not less than two years in such field after obtaining--

(i) any one of the medical qualifications recognised under the Indian Medical Council Act, 1956 (102 of 1956); or

(ii) a post-graduate degree in biological sciences;

**Clause (i) of section 2**

(i) "pre-natal diagnostic procedures" means all gynaecological or obstetrical or medical procedures such as ultrasonography foetoscopy, taking or removing samples of amniotic fluid, chorionic villi, blood or any tissue of a pregnant woman for being sent to a Genetic Laboratory or Genetic Clinic for conducting pre-natal diagnostic test;

### **Clause (k) of section 2**

(k) "pre-natal diagnostic test" means ultrasonography or any test or analysis of amniotic fluid, chorionic villi, blood or any tissue of a pregnant woman conducted to detect genetic or metabolic disorders or chromosomal abnormalities or congenital anomalies or haemoglobinopathies or sex-linked diseases;

### **Clause (2) of section 3**

(2) no Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall employ or cause to be employed any person who does not possess the prescribed qualifications;

### **Clauses (3) and (4) of section 4**

(3) no pre-natal diagnostic techniques shall be used or conducted unless the person qualified to do so is satisfied that any of the following conditions are fulfilled, namely:-

- (i) age of the pregnant woman is above thirty-five years;
- (ii) the pregnant woman has undergone of two or more spontaneous abortions or foetal loss;
- (iii) the pregnant woman had been exposed to potentially teratogenic agents such as drugs, radiation, infection or chemicals;
- (iv) the pregnant woman has a family history of mental retardation or physical deformities such as spasticity or any other genetic disease;
- (v) any other condition as may be specified by the Central Supervisory Board;

(4) no person, being a relative or the husband of the pregnant woman shall seek or encourage the conduct of any pre-natal diagnostic techniques on her except for the purpose specified in clause (2).

### **Sub-section (2) of section 5**

(2) No person conducting pre-natal diagnostic procedures shall communicate to the pregnant woman concerned or her relatives the sex of the foetus by words, signs or in any other manner.

**Clause (c) of sub-section (2) of section 7**

(c) two members to be appointed by the Central Government to represent the Ministries of Central Government in charge of woman and Child Development and of Law and Justice, ex officio;

**Sub-clause (ii) of clause (c) of sub-section (2) of section 7**

(ii) eminent gynaecologists and obstetricians;

**Clause (f) of section 14**

(f) has, in the opinion of the Central Government, been associated with the use or promotion of pre-natal diagnostic technique for determination of sex.

**Section 16**

**16. Functions of the Board**

The Board shall have the following functions, namely.—

- (i) to advise the Government on policy matters relating to use of pre-natal diagnostic techniques;
- (ii) to review implementation of the Act and the rules made thereunder and recommend changes in the said Act and rules to the Central Government;
- (iii) to create public awareness against the practice of pre-natal determination of sex and female foeticide;
- (iv) to lay down code of conduct to be observed by persons working at Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics;
- (v) any other functions as may be specified under the Act.

**Clause (a) of sub-section (3) of section 17**

- (a) when appointed for the whole of the State or the Union Territory, of or above the rank of the Joint Director of Health and Family Welfare; and

**Sub-section (7) of section 17**

(7) No person who, in the opinion of the Central Government or the State Government, as the case may be, has been associated with the use or promotion of pre-natal diagnostic technique for determination of sex shall be appointed as a member of the Advisory Committee.

**Sub-section (1) of section 18**

**18. Registration of Genetic Counselling Centres, Genetic Laboratories or Genetic Clinics**

(1) No person shall open any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic after the commencement of this Act unless such Centre, Laboratory or Clinic is duly registered separately or jointly under this Act.

**Section 22**

**22. Prohibition of advertisement relating to pre-natal determination of sex and punishment for contravention**

(1) No person, Organisation, Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall issue or cause to be issued any advertisement in any manner regarding facilities of pre-natal determination of sex available at such Centre, Laboratory, Clinic or any other place.

(2) No person or organisation shall publish or distribute or cause to be published or distributed any advertisement in any manner regarding facilities of pre-natal determination of sex available at any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic or any other place.

(3) Any person who contravenes the provisions of sub-section (1) or sub-section (2) shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to ten thousand rupees.

**Explanation.--**For the purposes of this section, "advertisement" includes any notice, circular, label wrapper or other document and also includes any visible representation made by means of any light, sound, smoke or gas.

**Sub-sections (2) and (3) of section 23**

(2) The name of the registered medical practitioner who has been convicted by the court under sub-section (1), shall be reported by the Appropriate Authority to the respective

State Medical Council for taking necessary action including the removal of his name from the register of the Council for a period of two years for the first offence and permanently for the subsequent offence.

(3) Any person who seeks the aid of a Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic or of a medical geneticist, gynaecologist or registered medical practitioner for conducting pre-natal diagnostic techniques on any pregnant woman (including such woman unless she was compelled to undergo such diagnostic techniques) for purposes other than those specified in clause (2) of section 4, shall, be punishable with imprisonment for a term which may extend to three years and with fine which may extend to ten thousand rupees and on any subsequent conviction with imprisonment which may extend to five years and with fine which may extend to fifty thousand rupees.

## **Section 24**

### **24. Presumption in the case of conduct of pre-natal diagnostic techniques**

Notwithstanding anything in the Indian Evidence Act, 1872 (1 of 1872), the court shall presume unless the contrary is proved that the pregnant woman has been compelled by her husband or the relative to undergo pre-natal diagnostic technique and such person shall be liable for abetment of offence under sub-section (3) of section 23 and shall be punishable for the offence specified under that section.

## **Sub-section (1) section 30**

### **30. Power to search and seize records, etc**

(1) If the Appropriate Authority has reason to believe that an offence under this Act has been or is being committed at any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, such Authority or any officer authorised thereof in this behalf may, subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such authority or officer considers necessary, such Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize the same if such Authority or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

**Clause (i) of sub-section (2) of section 32**

- (i) the minimum qualifications for persons employed at a registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic under clause (1) of section 3;

**PRENATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION) RULES, 1996**

**1. Short title and commencement.--**

(1) These rules may be called the Preconception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996.

(2) They shall come into force on the date of their publication in the Official Gazette.

**2. Definitions.--**

In these rules, unless the context otherwise requires :

(a) "Act" means The Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994);

(b) "Employee" means a person working in or employed by a Genetic Counselling Centre, a Genetic Laboratory or a Genetic Clinic, and includes those working on parttime, contractual, consultancy, honorary or on any other basis;

(c) "Form" means a Form appended to these rules;

(d) xxxx

(e) "Section" means a section of the Act;

(f) Words and expressions used herein and not defined in these rules but defined in the Act, shall have the meanings, respectively, assigned to them in the Act.

**3. The qualifications of the employees, the requirement of equipment etc. for a Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall be as under:-**

(1) Any person being or employing

(i) A gynaecologist or a paediatrician having six months experience or four weeks training in genetic counseling or

(ii) A medical geneticist, having adequate space and educational charts/models/equipments for carrying out genetic counseling may set up a genetic counseling center and get it registered as a genetic counseling center.

**(2) (a) Any person having adequate space and being or employing**

**(i) a Medical Geneticist and**

**(ii) a laboratory technician having a B.Sc. degree in Biological Sciences or a degree or diploma in medical laboratory course with at least one year experience in conducting appropriate prenatal diagnostic techniques, tests or procedures may set up a genetic laboratory.**

**(b) Such laboratory should have or acquire such of the following equipments as may be necessary for carrying out chromosomal studies, biochemical studies and molecular studies :**

**(i) Chromosomal studies:**

**(1) Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.**

**(2) Photomicroscope with fluorescent source of light.**

**(3) Inverted microscope.**

**(4) Incubator and oven.**

**(5) Carbondioxide incubator or closed system with 5% CO<sub>2</sub> atmosphere.**

**(6) Autoclave.**

**(7) Refrigerator.**

**(8) Water bath.**

**(9) Centrifuge.**

**(10) Vortex mixer.**

**(11) Magnetic stirrer.**

**(12) pH meter.**

**(13) A sensitive balance (preferable electronic) with sensitivity of 0.1 milligram.**

**(14) Double distillation apparatus (glass).**

- (15) Such other equipments as may be necessary.
- (ii) Biochemical studies: (requirements according to tests to be carried out)
- (1) Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.
  - (2) Inverted microscope.
  - (3) Incubator and oven.
  - (4) Carbondioxide incubator or closed system with 5% CO<sub>2</sub> atmosphere.
  - (5) Autoclave.
  - (6) Refrigerator.
  - (7) Water bath.
  - (8) Centrifuge.
  - (9) Electrophoresis apparatus and power supply.
  - (10) Chromatography chamber.
  - (11) Spectrophotometer and Elisa reader or Radioimmunoassay system (with gamma betacounter) or fluorometer for various biochemical test.
  - (12) Vortex mixer.
  - (13) Magnetic stirrer.
  - (14) pH meter.
  - (15) A sensitive balance (preferable electronic) with sensitivity of 0.1 milligram.
  - (16) Double distillation apparatus (glass).
  - (17) Liquid nitrogen tank.
  - (18) Such other equipments as may be necessary.

**(iii) Molecular studies:**

- (1) Inverted microscope.**
  - (2) Incubator.**
  - (3) Oven.**
  - (4) Autoclave.**
  - (5) Refrigerators (4 degree and minus 20 degree Centigrade).**
  - (6) Water bath.**
  - (7) Microcentrifuge.**
  - (8) Electrophoresis apparatus and power supply.**
  - (9) Vortex mixer.**
  - (10) Magnetic stirrer.**
  - (11) pH meter.**
  - (12) A sensitive balance (preferable electronic) with sensitivity of 0.1 milligram.**
  - (13) Double distillation apparatus (glass).**
  - (14) P.C.R. machine.**
  - (15) Refrigerated centrifuge.**
  - (16) U.V. Illuminator with photographic attachment or other documentation system.**
  - (17) Precision micropipettes.**
  - (18) Such other equipments as may be necessary.**
- (3) (1) Any person having adequate space and being or employing**
- (a) Gynaecologist having experience of performing at least 20 procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, Cordocentesis foetoscopy, foetal**

skin or organ biopsy or foetal blood sampling etc. Under supervision of an experienced gynaecologist in these fields, or

§{(b) a sonologist or imaging specialist or registered medical practitioner having Post Graduate degree or diploma or six months training duly imparted in the manner prescribed in the "the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014; or]

(c) A medical geneticist May set up a genetic clinic/ultrasound clinic/imaging center.

(2) The Genetic Clinic/ultrasound clinic/imaging center should have or acquire such of the following equipments, as may be necessary for carrying out the tests or procedures

(a) Equipment and accessories necessary for carrying out clinical examination by an obstetrician or gynaecologist

(b) An ultrasonography machine including mobile ultrasound machine, imaging machine or any other equipment capable of conducting foetal ultrasonography.

(c) Appropriate catheters and equipment for carrying out chorionic villi aspirations per vagina or per abdomen.

(d) Appropriate sterile needles for amniocentesis or cordocentesis.

(e) A suitable foetoscopy with appropriate accessories for foetoscopy, foetal skin or organ biopsy or foetal blood sampling shall be optional.

(f) Equipment for dry and wet sterilization.

(g) Equipment for carrying out emergency procedures such as evacuation of uterus or resuscitation in case of need.

(h) Genetic Works Station.

<sup>2</sup>[(3) Each medical practitioner qualified under the Act to conduct ultrasonography in a genetic clinic/ ultrasound clinic/imaging centre shall be permitted to be registered with a maximum of two such clinics/centres within a district. The consulting hours for such medical practitioner, shall be clearly specified by each clinic/centre.]

**3A. Sale of ultrasound machines/imaging machines.—**

(1) No organization including a commercial organization or a person, including manufacturer, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment, capable of detecting sex of foetus, shall sell, distribute, supply, rent, allow or authorize the use of any such machine or equipment in any manner, whether on payment or otherwise, to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person unless such Centre, Laboratory, Clinic, body or person is registered under the Act.

(2) The provider of such machine/equipment to any person/body registered under the Act shall send to the concerned State/UT Appropriate Authority and to the Central Government, once in three months a list of those to whom the machine/equipment has been provided.

(3) Any organization or person, including manufacturer, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment capable of detecting sex of foetus selling, distributing, supplying or authorizing in any manner, the use of any such machine or equipment to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person registered under the Act shall take an affidavit from such body or person purchasing or getting authorization for using such machine/equipment that the machine/equipment shall not be used for detection of sex of foetus or selection of sex before or after conception.

**4. Registration of Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic.—**

(1) An application for registration shall be made to the Appropriate Authority, in duplicate, in Form A, duly accompanied by an Affidavit containing

(i) an undertaking to the effect that the Genetic Centre/Laboratory/Clinic/ Ultrasound Clinic/Imaging Centre/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 foetus be disclosed to any body; and

(ii) an undertaking to the effect that the Genetic Centre/Laboratory/Clinic/ combination thereof, as the case may be, shall display prominently a notice that they do not conduct any technique, test or procedure etc. By whatever

name called, for detection of sex of foetus or for selection of sex before or after conception.

(2) The Appropriate Authority, or any person in his office authorized in this behalf, shall acknowledge receipt of the application for registration, in the acknowledgement slip provided at the bottom of Form A, immediately if delivered at the office of the Appropriate Authority, or not later than the next working day if received by post.

#### 5. Application Fee.--

(1) Every application for registration under rule 4 shall be accompanied by an application fee of :

(a) <sup>3</sup>[rupees twenty five thousand] for Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre.

(b) <sup>4</sup>[rupees thirty five thousand] for an institute, hospital, nursing home, or any place providing jointly the service of a Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic, Ultrasound Clinic or Imaging Centre or any combination thereof.

Provided that if an application for registration of any Genetic Clinic/Laboratory/Centre etc. has been rejected by the Appropriate Authority, no fee shall be required to be paid on resubmission of the application by the applicant for the same body within 90 days of rejection. Provided further that any subsequent application shall be accompanied with the prescribed fee. Application fee once paid will not be refunded.

(2) The application fee shall be paid by a demand draft drawn in favour of the Appropriate Authority, on any scheduled bank payable at the head quarters of the Appropriate Authority concerned. The fees collected by the Appropriate Authority for registration of Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre or any other body or person under subrule (1), shall be deposited by the Appropriate Authority concerned in a bank account opened in the name of the official designation of the Appropriate Authority concerned and shall be utilized by the Appropriate Authority in connection with the activities connected with implementation of the provisions of the Act and these rules.

**6. Certificate of registration.--**

- (1) The Appropriate Authority shall, after making such enquiry and after satisfying itself that the applicant has complied with all the requirements, place the application before the Advisory Committee for its advice.
- (2) Having regard to the advice of the Advisory Committee the Appropriate Authority shall grant a certificate of registration, in duplicate, in Form B to the applicant. One copy of the certificate of registration shall be displayed by the registered Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre at a conspicuous place at its place of business: Provided that the Appropriate Authority may grant a certificate of registration to a Genetic Laboratory or a Genetic Clinic, Ultrasound Clinic or Imaging Centre to conduct one or more specified prenatal diagnostic tests or procedures, depending on the availability of place, equipment and qualified employees, and standards maintained by such laboratory or clinic.
- (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 these rules, it shall, for the reasons to be recorded in writing, reject the application for registration and communicate such rejection to the applicant as specified in Form C.
- (4) An enquiry under subrule(1), including inspection at the premises of the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre, shall, be carried out only after due notice is given to the applicant by the Appropriate Authority.
- (5) Grant of certificate of registration or rejection of application for registration shall be communicated to the applicant as specified in Form B or Form C, as the case may be, within a period of ninety days from the date of receipt of application for registration.
- (6) The certificate of registration shall be nontransferable. In the event of change of ownership or change of management or on ceasing to function as a Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre, both copies, of the certificate of registration shall be surrendered to the Appropriate Authority.
- (7) In the event of change of ownership or change of management of the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging

Centre, the new owner or manager of such Centre, Laboratory or Clinic shall apply afresh for grant of certificate of registration.

**7. Validity of registration.—**

Every certificate of registration shall be valid for a period of five years from the date of its issue.

**8. Renewal of registration.—**

(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. Acknowledgement of receipt of such application shall be issued by the Appropriate Authority in the manner specified in subrule (2) of rule 4.

(2) The Appropriate Authority shall, after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of the Act and these rules and having regard to the advice of the Advisory Committee in this behalf, renew the certificate of registration, as specified in Form B, for a further period of five years from the date of expiry of the certificate of registration earlier granted.

(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 these rules, it shall, for reasons to be recorded in writing, reject the application for renewal of certificate of registration and communicate such rejection to the applicant as specified in Form C.

(4) The fees payable for renewal of certificate of registration shall be one half of the fees provided in subrule (1) of rule 5.

(5) On receipt of the renewed certificate of registration in duplicate or on receipt of communication of rejection of application for renewal, both copies of the earlier certificate of registration shall be surrendered immediately to the Appropriate Authority by the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre.

(6) In the event of failure of the Appropriate Authority to renew the certificate of registration or to communicate rejection of application for renewal of registration within a period of ninety days from the date of receipt of application for renewal of registration, the certificate of registration shall be deemed to have been renewed.

**9. Maintenance and preservation of records.--**

- (1) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall maintain a register showing, in serial order, the names and addresses of the men or women given genetic counseling, subjected to prenatal diagnostic procedures or prenatal diagnostic tests, the names of their spouses or fathers and the date on which they first reported for such counseling, procedure or test.
- (2) The record to be maintained by every Genetic Counselling Centre, in respect of each woman counselled shall be as specified in Form D.
- (3) The record to be maintained by every Genetic Laboratory, in respect of each man or woman subjected to any prenatal diagnostic procedure/technique/test, shall be as specified in Form E.
- (4) The record to be maintained by every Genetic Clinic, in respect of each man or woman subjected to any prenatal diagnostic procedure/technique/test, shall be as specified in Form F.
- (5) The Appropriate Authority shall maintain a permanent record of applications for grant or renewal of certificate of registration as specified in Form H. Letters of intimation of every change of employee, place, address and equipment installed shall also be preserved as permanent records.
- (6) 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, Genetic Clinic, Ultrasound Clinic or Imaging Centre for a period of two years from the date of completion of counseling, prenatal diagnostic procedure or prenatal 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.
- (7) In case the Genetic Counselling Centre or Genetic Laboratory, Genetic Clinic, Ultrasound 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 by a person responsible for such record.
- (8) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall send a complete report in respect of all preconception 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.

**10. Conditions for conducting prenatal diagnostic procedures.--**

(1) Before conducting preimplantation genetic diagnosis, or any prenatal diagnostic technique/test/procedure such as amniocentesis, chorionic villi biopsy, foetal skin or organ biopsy or cordocentesis, a written consent, as specified in Form G, in a language the person undergoing such procedure understands, shall be obtained from her/him: Provided that where a Genetic Clinic has taken a sample of any body tissue or body fluid and sent it to a Genetic Laboratory for analysis or test, it shall not be necessary for the Genetic Laboratory to obtain a fresh consent in Form G. (1A) Any person conducting ultrasonography/image scanning on a pregnant woman shall give a declaration on each report on ultrasonography/image scanning that he/she has neither detected nor disclosed the sex of foetus of the pregnant woman to anybody. The pregnant woman shall before undergoing ultrasonography/image scanning declare that she does not want to know the sex of her foetus.

(2) All the State Governments and Union Territories may issue translation of Form G in languages used in the State or Union Territory and where no official translation in a language understood by the pregnant woman is available, the Genetic Clinic may translate Form G into a language she understands.

**11. Facilities for inspection.--**

(1) Every Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic, Ultrasound Clinic, Imaging Centre, nursing home, hospital, institute or any other place where any of the machines or equipments capable of performing any procedure, technique or prenatal determination of sex or selection of sex before or after conception is used, shall afford all reasonable facilities for inspection of the place, equipment and records to the Appropriate Authority or to any other person authorized by the Appropriate Authority in this behalf for registration of such institutions, by whatever name called, under the Act, or for detection of misuse of such facilities or advertisement therefore or for selection of sex before or after conception or for detection/disclosure of sex of foetus or for detection of cases of violation of the provisions of the Act in any other manner.

<sup>1</sup>[(2) The Appropriate Authority or the officer authorised by it may seal and seize any ultrasound machine, scanner or any other equipment, capable of detecting sex of foetus, used by any organization if the organization has not got itself registered under

the Act. These machines of such organizations shall be confiscated and further action shall be taken as per the provisions of the Section 23 of the Act.]

## **12. Procedure for search and seizure.—**

(1) The Appropriate Authority or any officer authorized in this behalf may enter and search at all reasonable times any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Imaging Centre or Ultrasound Clinic in the presence of two or more independent witnesses for the purposes of search and examination of any record, register, document, book, pamphlet, advertisement, or any other material object found therein and seal and seize the same if there is reason to believe that it may furnish evidence of commission of an offence punishable under the Act.

Explanation: In these Rules

(1) 'Genetic Laboratory/Genetic Clinic/Genetic Counselling Centre' would include an ultrasound center/imaging center/nursing home/hospital/institute or any other place, by whatever name called, where any of the machines or equipments capable of selection of sex before or after conception or performing any procedure, technique or test for prenatal detection of sex of foetus is used;

(2) 'material object' would include records, machines and equipments; and

(3) 'seize' and 'seizure' would include 'seal' and 'sealing' respectively.

(2) A list of any document, record, register, book, pamphlet, advertisement or any other material object found in the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre and seized shall be prepared in duplicate at the place of effecting the seizure. Both copies of such list shall be signed on every page by the Appropriate Authority or the officer authorized in this behalf and by the witnesses to the seizure: Provided that the list may be prepared, in the presence of the witnesses, at a place other than the place of seizure if, for reasons to be recorded in writing, it is not practicable to make the list at the place of effecting the seizure.

(3) One copy of the list referred to in subrule (2) shall be handed over, under acknowledgement, to the person from whose custody the document, record, register, book, pamphlet, advertisement or any other material object have been seized: Provided that a copy of the list of such document, record, register, book, pamphlet, advertisement or other material object seized may be delivered under

acknowledgement, or sent by registered post to the owner or manager of the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre, if no person acknowledging custody of the document, record, register, book, pamphlet, advertisement or other material object seized is available at the place of effecting the seizure.

(4) If any material object seized is perishable in nature, the Appropriate Authority, or the officer authorized in this behalf shall make arrangements promptly for sealing, identification and preservation of the material object and also convey it to a facility for analysis or test, if analysis or test be required: Provided that the refrigerator or other equipment used by the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre for preserving such perishable material object may be sealed until such time as arrangements can be made for safe removal of such perishable material object and in such eventuality, mention of keeping the material object seized, on the premises of the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre shall be made in the list of seizure.

(5) In the case of noncompletion of search and seizure operation, the Appropriate Authority or the officer authorized in this behalf may make arrangement, by way of mounting a guard or sealing of the premises of the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic Ultrasound Clinic or Imaging Centre, for safe keeping, listing and removal of documents, records, book or any other material object to be seized, and to prevent any tampering with such documents, records, books or any other material object.

### **13. Intimation of changes in employees, place or equipment.—**

Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall intimate every change of employee, place, address and equipment installed, to the Appropriate Authority<sup>5</sup>[at least thirty days in advance of the expected date of such change, and seek re-issuance of certificate of registration from the Appropriate Authority, with the changes duly incorporated].

### **14. Conditions for analysis or test and prenatal diagnostic procedures.—**

(1) No Genetic Laboratory shall accept for analysis or test any sample, unless referred to it by a Genetic Clinic.

(2) Every prenatal diagnostic procedure shall invariably be immediately preceded by locating the fetus and placenta through ultrasonography, and the prenatal diagnostic

procedure shall be done under direct ultrasonography monitoring so as to prevent any damage to the fetus and placenta.

**15. Meetings of the Advisory Committees.--**

The intervening period between any two meetings of Advisory Committees constituted under subsection (5) of Section 17 to advise the Appropriate Authority shall not exceed sixty days.

**16. Allowances to members of the Central Supervisory Board.--**

(1) The exofficio members, and other Central and State Government officers appointed to the Board will be entitled to Travelling Allowance and Daily Allowance for attending the meetings of the Board as per the Travelling Allowance rules applicable to them.

(2) The nonofficial members appointed to, and Members of Parliament elected to the Board will be entitled to Travelling Allowance and Daily Allowance for attending the meetings of the Board as admissible to nonofficial and Members of Parliament as the case may be, under the Travelling Allowances rules of the Central Government.

**17. Public Information.--**

(1) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and 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, to effect that disclosure of the sex of the foetus is prohibited under law.

(2) At least one copy each of the Act and these rules shall be available on the premises of every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre, and shall be made available to the clientele on demand for perusal.

(3) The Appropriate Authority, the Central Government, the State Government, and the Government/Administration of the Union Territory may publish periodically lists of registered Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics and Imaging Centres and findings from the reports and other information in their possession, for the information of the public and for use by the experts in the field.

**18. Code of Conduct to be observed by persons working at Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics, Imaging Centres etc.--**

All persons including the owner, employee or any other person associated with Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics, Imaging Centres registered under the Act/these Rules shall

- i. not conduct or associate with, or help in carrying out detection or disclosure of sex of foetus in any manner;
- ii. not employ or cause to be employed any person not possessing qualifications necessary for carrying out prenatal diagnostic techniques/procedures and tests including ultrasonography;
- iii. not conduct or cause to be conducted or aid in conducting by himself or through any other person any techniques or procedure for selection of sex before or after conception or for detection of sex of foetus except for the purposes specified in subsection (2) of section 4 of the Act;
- iv. not conduct or cause to be conducted or aid in conducting by himself or through any other person any techniques or test or procedure under the Act at a place other than a place registered under the Act/the Rules;
- v. ensure that no provision of the Act and these Rules are violated in any manner;
- vi. ensure that the person conducting any techniques, test or procedure leading to detection of sex of foetus for purposes not covered under section 4(2) of the Act or selection of sex before or after conception, is informed that such procedures lead to violation of the Act and the Rules which are punishable offences;
- vii. help the law enforcing agencies in bringing to book the violators of the provisions of the Act and the Rules;
- viii. display his/her name and designation prominently on the dress worn by him/her;
- ix. write his/her name and designation in full under his/her signature;
- x. on no account conduct or allow/cause to be conducted female foeticide;
- xi. not commit any other act of professional misconduct.

**18-A. Code of Conduct to be observed by Appropriate Authorities.--**

(1) All the Appropriate Authorities Including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following general code of conduct, namely:-

- (i) maintain dignity, and integrity at all times;
- (ii) observe and implement the provisions of the Act and Rules in a balanced and standardised manner in the course of their work;
- (iii) conduct their work in a just manner without any bias or a perceived presumption of guilt;
- (iv) refrain from making any comments which demean individuals on the basis of gender, race, religion;
- (v) delegate his or her powers by administrative order to any authorised officer in his or her absence and preserve the order of authorisation as documentary proof for further action.

(2) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following Conduct for Advisory Committees, namely:-

- (i) ensure that the re-constitution, functions and other relevant matters related to advisory committee shall be in accordance with the provisions of the Advisory Committee Rules, 1996;
- (ii) ensure that a person who is the part of investigating machinery in cases under the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994), shall not be nominated or appointed as a member of the Advisory Committee;
- (iii) ensure that the process of filling up of vacancies in Advisory Committee shall start at least ninety days before the probable date of the occurrence of vacancy;
- (iv) ensure that no person shall participate as a member or a legal expert of the Advisory Committee if he or she has conflict of interest;
- (v) conduct frequent meetings of the Advisory Committee to expedite the decisions regarding renewal, cancellation and suspension of registration.

(3) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for processing of complaint and investigation, namely:--

- (i) maintain appropriate diaries in support of registration of each of the complaint or case under the Act;
- (ii) attend to all complaints and maintain transparency in the follow-up action of the complaints;
- (iii) investigate all the complaints within twenty four hours of receipt of the complaint and complete the investigation within forty-eight hours of receipt of such compliant;
- (iv) as far as possible, not involve police for investigating cases under the Act as the cases under the Act are tried as complaint cases under the Code of Criminal Procedure, 1973 (2 of 1974).

(4) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for registration and renewal of applications under the Act, namely:--

- (i) dispose of the application for renewal and new registration within a period of seventy days from the date of receipt of application;
- (ii) ensure that no application for fresh registration or renewal is accepted if any case is pending in any court against the applicant.

(5) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for Legal Action, namely:--

- (i) ensure that protection and expenses of witness shall be met from the registration amount collected;
- (ii) ensure that all the notifications of the Government be produced in original in the court and a copy of the same be preserved;
- (iii) ensure that while filing the cases, all the papers, records, statements, evidence, panchnama and other material objects attached to the case file shall be in original;

(iv) suspend the certificate of registration in the course of taking legal action of seizure and sealing of the facility;

(v) ensure that there shall be no violation of the provisions of the Medical Termination Pregnancy Act, 1971 (34 of 1971) and the Rules made thereunder while implementing the provisions of the Pre-conception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996;

(vi) take immediate action for filing appeal, revision or other proceeding in higher courts in case of order of acquittal within a period of thirty days but not later than fifteen days of receipt of the order of acquittal.

(6) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall submit quarterly progress report to the Government of India through State Government and maintain Form H for keeping the information of all the registrations made readily available.

(7) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following regulation of ultrasound equipments, namely:--

(i) monitor the sales and import of ultrasound machines including portable or buyback, assembled, gift, scrap or demo;

(ii) ensue regular quarterly reports from ultrasound manufacturers, dealers, wholesalers and retailers and any person dealing with the sales of ultrasound machines at the State level;

(iii) conduct periodical survey and audit of all the ultrasound machines sold and operating in the State or district to identify the unregistered machines;

(iv) file complaint against any owner of the unregistered ultrasound machine and against the seller of the unregistered ultrasound machine.

(8) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for inspection and monitoring, namely:--

(i) conduct regular inspection of all the registered facilities once in every ninety days and shall preserve the inspection report as documentary evidence and a copy of the same be handed over to the owner of facility inspected and obtain acknowledgement in respect of the inspection;

(ii) place all the inspection reports once in three months before the Advisory Committee for follow up action;

(iii) maintain bimonthly progress report containing number of cases filed and persons convicted, registration made, suspended or cancelled, medical licenses cancelled, suspended, inspections conducted, Advisory Committee meetings held at the district level and quarterly progress report at the State level;

(iv) (a) procure the copy of the charges framed within seven days and in the case of doctors, the details of the charges framed shall be submitted within seven days of the receipt of copy of charges framed to the State Medical Council;

(b) procure the certified copy of the order of conviction as soon as possible and in the case of conviction of the doctors, the certified copy of the order of conviction shall be submitted within seven days of the receipt of copy of the order of conviction.

(9) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for accountability, namely:--

(i) obtain prior sanction or approval of the Government of India for any resolution concerning the implementation of the provisions of the Act;

(ii) take action, if any, required under the Act and immediately on receipt of notice under clause (b) of sub-section (1) of section 28 of the Act and if he or she fails to do so, shall not be entitled for the protection under section 31 of the said Act and defend the case in his or her own capacity and at his or her own cost.

(10) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall follow the following financial guidance, namely:--

(i) maintain a separate and independent bank account operated by two officers jointly, at all levels;

(ii) ensure transparency and adherence to standard Government financial norms for disbursement of money.]

**19. Appeals.—**

- (1) Anybody aggrieved by the decision of the Appropriate Authority at subdistrict level may appeal to the Appropriate Authority at district level within 30 days of the order of the subdistrict level Appropriate Authority.
- (2) Anybody aggrieved by the decision of the Appropriate Authority at district level may appeal to the Appropriate Authority at State/UT level within 30 days of the order of the District level Appropriate Authority.
- (3) Each appeal shall be disposed of by the District Appropriate Authority or by the State/Union Territory Appropriate Authority, as the case may be, within 60 days of its receipt.

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1. Substituted by the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Amendment Rules, 2011 vide Notification No. GSR426(E) dated 31.05.2011 for the following : -

"(2) The Appropriate Authority or the officer authorized by it may seal and seize any ultrasound machine, scanner or any other equipment, capable of detecting sex of foetus, used by any organization if the organization has not got itself registered under the Act. These machines of the organizations may be released if such organization pays penalty equal to five times of the registration fee to the Appropriate Authority concerned and gives an undertaking that it shall not undertake detection of sex of foetus or selection of sex before or after conception."

2. Inserted by the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Amendment Rules, 2012 vide Notification No. GSR418(E) dated 04.06.2012 w.e.f. 05.06.2012.

3. Substituted by the by the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Amendment Rules, 2012 vide Notification No. GSR418(E) dated 04.06.2012 w.e.f. 05.06.2012 for the following : -"Rs.3000.00"

4. Substituted by the by the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Amendment Rules, 2012 vide Notification No. GSR418(E) dated 04.06.2012 w.e.f. 05.06.2012 for the following : - "Rs. 4000.00"

5. Substituted by the by the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Amendment Rules, 2012 vide Notification No. GSR418(E) dated 04.06.2012 w.e.f. 05.06.2012 for the following : - "within a period of thirty days of such change"

6. Substituted by the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Amendment Rules, 2014 vide Notification No. GSR13(E) Dated 09.01.2014 for the following : -

"(b) A Sonologist, Imaging Specialist, Radiologist or Registered Medical Practitioner having Post Graduate degree or diploma or six months training or one year experience in sonography or image scanning, or"

7. Inserted by the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Amendment Rules, 2014 vide Notification No. GSR119(E) dated 24.02.2014 w.e.f 26.02.2014.

**THE PRE-NATAL DIAGNOSTIC TECHNIQUES  
(REGULATION AND PREVENTION OF MISUSE) RULES, 1996**

**1. Short title and commencement.**-<sup>1</sup>[(1) These Rules may be called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996.]

(2) They shall come into force on the date of their publication in the Official Gazette.

**2. Definitions.**- In these rules, unless the context otherwise requires:-

- (a) "Act" means The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994);
- (b) "employee" means a person working in or employed by a Genetic Counselling Centre, a Genetic Laboratory or a Genetic Clinic, and includes those working on part-time, contractual, consultancy, honorary or on any other basis;
- (c) "Form" means a Form appended to these rules;
- (d) <sup>2</sup>[\*\*\*]
- (e) "Section" means a section of the Act;
- (f) words and expressions used herein and not defined in these rules but defined in the Act, shall have the meanings, respectively, assigned to them in the Act.

<sup>3</sup>[(3. The qualifications of the employees, the requirement of equipment etc. for a Genetic Counseling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall be as under:

(1) Any person being or employing

- (i) a gynaecologist or a paediatrician having six months experience or four weeks training in genetic counseling or
- (ii) a medical geneticists,

having adequate space and educational charts/models/equipments for carrying out genetic counselling may set up a genetic counselling center and get it registered as a genetic counselling center.

(2) (a) Any person having adequate space and being or employing

(i) a Medical Geneticist and

(ii) a laboratory technician, having a B.Sc. degree in Biological Sciences or a degree or diploma in medical laboratory course with at least one year experience in conducting appropriate prenatal diagnostic techniques, tests or procedures may set up a genetic laboratory.

(b) Such laboratory should have or acquire such of the following equipments as may be necessary for carrying out chromosomal studies, bio-chemical studies and molecular studies:-

(i) Chromosomal studies:

(1) Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.

(2) Photo-microscope with fluorescent source of light.

(3) Inverted microscope.

(4) Incubator and oven.

(5) Carbon dioxide incubator or closed system with 5% CO<sub>2</sub> atmosphere.

(6) Autoclave.

(7) Refrigerator.

(8) Water bath.

(9) Centrifuge.

(10) Vortex mixer.

(11) Magnetic stirrer.

(12) pH Meter.

(13) A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.

(14) Double distillation apparatus (glass).

(15) Such other equipments as may be necessary.

(ii) Biochemical studies:

(requirements according to tests to be carried out)

(1) Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.

(2) Inverted microscope.

(3) Incubator and oven.

(4) Carbon dioxide incubator or closed system with 5% CO<sub>2</sub> atmosphere.

(5) Autoclave.

(6) Refrigerator. (7) Water bath.

(8) Centrifuge.

(9) Electrophoresis apparatus and power supply.

(10) Chromatography chamber.

(11) Spectro-photometer and Elisa reader or Radio-immunoassay system (with gamma beta-counter) or fluorometer for various biochemical tests.

(12) Vortex mixer. (13) Magnetic stirrer.

(14) pH meter.

(15) A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.

(16) Double distillation apparatus (glass).

**(17) Liquid nitrogen tank.**

**(18) Such other equipments as may be necessary.**

**(iii) Molecular studies:**

- (1) Inverted microscope.**
- (2) Incubator.**
- (3) Oven.**
- (4) Autoclave.**
- (5) Refrigerators (4 degree and minus 20 degree Centigrade).**
- (6) Water bath.**
- (7) Microcentrifuge.**
- (8) Electrophoresis apparatus and power supply.**
- (9) Vertex mixer.**
- (10) Magnetic stirrer.**
- (11) pH meter.**
- (12) A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.**
- (13) Double distillation apparatus (glass).**
- (14) P.C.R. machine.**
- (15) Refrigerated centrifuge.**
- (16) U.V. Illuminator with photographic attachment or other documentation system.**
- (17) Precision micropipettes.**
- (18) Such other equipments as may be necessary.**

(3) (1) Any person having adequate space and being or employing

(a) Gynaecologist having experience of performing at least 20 procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis foetoscopy, foetal skin or organ biopsy or foetal blood sampling etc. under supervision of an experienced gynaecologist in these fields, or

(b) a Sonologist, Imaging Specialist, Radiologist or Registered Medical Practitioner having Post Graduate degree or diploma or six months training or one year experience in sonography or image scanning, or.

(c) A medical geneticist:

may set up a genetic clinic/ultrasound clinic/imaging centre.

(2) The Genetic Clinic/ultrasound clinic/imaging centre should have or acquire such of the following equipments, as may be necessary for carrying out the tests or procedures -

(a) Equipment and accessories necessary for carrying out clinical examination by an obstetrician or gynaecologist.

(b) An ultra-sonography machine including mobile ultrasound machine, imaging machine or any other equipment capable of conducting foetal ultrasonography.

(c) Appropriate catheters and equipment for carrying out chorionic villi aspirations per vagina or per abdomen.

(d) Appropriate sterile needles for amniocentesis or cordocentesis.

(e) A suitable foetoscope with appropriate accessories for foetoscopy, foetal skin or organ biopsy or foetal blood sampling shall be optional.

(f) Equipment for dry and wet sterilization.

(g) Equipment for carrying out emergency procedures such as evacuation of uterus or resuscitation in case of need.

(g) Genetic Works Station.]

**3A. Sale of ultrasound machines/imaging machines:**

(1) No organization including a commercial organization or a person, including manufacturer, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment, capable of detecting sex of foetus, shall sell distribute, supply, rent, allow or authorize the use of any such machine or equipment in any manner, whether on payment or otherwise, to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person unless such Centre, Laboratory, Clinic, body or person is registered under the Act.

(2) The provider of such machine/equipment to any person/body registered under the Act shall send to the concerned State/UT Appropriate Authority and to the Central Government, once in three months a list of those to whom the machine/equipment has been provided.

(3) Any organization or person, including manufacturer, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment capable of detecting sex of foetus selling, distributing, supplying or authorizing, in any manner, the use of any such machine or equipment to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person registered under the Act shall take an affidavit from the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person purchasing or getting authorization for using such machine /equipment that the machine/equipment shall not be used for detection of sex of foetus or selection of sex before or after conception.]

**4. Registration of Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres.-**

<sup>5</sup>[(1) An application for registration shall be made to the Appropriate Authority, in duplicate, in Form A, duly accompanied by an Affidavit containing-

- (i) an undertaking to the effect that the Genetic Centre/Laboratory/ Clinic/ Ultrasound Clinic/ Imaging Centre/ 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 foetus be disclosed to any body; and
- (ii) an undertaking to the effect that the Genetic Centre/Laboratory/ Clinic/ Combination thereof, as the case may be, shall display prominently a notice that they do not conduct any technique, test or procedure etc. by whatever name called, for detection of sex of foetus or for selection of sex before or after conception.]

(2) The Appropriate Authority, or any person in his office authorized in this behalf, shall acknowledge receipt of the application for registration, in the acknowledgement slip provided at the bottom of Form A, immediately if delivered at the office of the Appropriate Authority, or not later than the next working day if received by post.

**5. Application Fee** - (1) Every application for registration under Rule 4 shall be accompanied by an application fee of :-

(a) Rs. 3000.00 for Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre.

(b) Rs. 4000.00 for an institute, hospital, nursing home, or any place providing jointly the service of a Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres, Ultrasound Clinic or Imaging Centre or any combination thereof.

Provided that if an application for registration of any Genetic Clinic/ Laboratory/ Centre etc. has been rejected by the Appropriate Authority, no fee shall be required to be paid on re-submission of the application by the applicant for the same body within 90 days of rejection. Provided further that any subsequent application shall be accompanied with the prescribed fee. Application fee once paid will not be refunded.

(2) The application fee shall be paid by a demand draft drawn in favour of the Appropriate Authority, on any scheduled bank payable at the headquarters of the Appropriate Authority concerned. The fees collected by the Appropriate

Authorities for registration of Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre or any other body or person under sub-rule (1), shall be deposited by the Appropriate Authority concerned in a bank account opened in the name of the official designation of the Appropriate Authority concerned and shall be utilized by the Appropriate Authority in connection with the activities connected with implementation of the provisions of the Act and these rules.]

**6. Certificate of registration.**- (1) The Appropriate Authority shall, after making such enquiry and after satisfying itself that the applicant has complied with all the requirements, place the application before the Advisory Committee for its advice.

(2) Having regard to the advice of the Advisory Committee the Appropriate Authority shall grant a certificate of registration, in duplicate, in Form B to the applicant. One copy of the certificate of registration shall be displayed by the registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic at a conspicuous place at its place of business:

Provided that the Appropriate Authority may grant a certificate of registration to a Genetic Laboratory or a Genetic Clinic to conduct one or more specified pre-natal diagnostic tests or procedures, depending on the availability of place, equipment and qualified employees, and standards maintained by such laboratory or clinic.

(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 these rules, it shall, for the reasons to be recorded in writing, reject the application for registration and communicate such rejection to the applicant as specified in Form C.

(4) An enquiry under sub-rule(1), including inspection at the premises of the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, shall, be carried out only after due notice is given to the applicant by the Appropriate Authority.

(5) Grant of certificate of registration or rejection of application for registration shall be communicated to the applicant as specified in Form B or Form C, as the case may be, within a period of ninety days from the date of receipt of application for registration.

(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, both copies, of the certificate of registration shall be surrendered to the Appropriate Authority.

(7) In the event of change of ownership or change of management of the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, the new owner or manager of such Centre, Laboratory or Clinic shall apply afresh for grant of certificate of registration.

**7. Validity of registration.**- Every certificate of registration shall be valid for a period of five years from the date of its issue.

**8. Renewal of registration.**- (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. Acknowledgement of receipt of such application shall be issued by the Appropriate Authority in the manner specified in sub-rule (2) of rule 4.

(2) The Appropriate Authority shall, after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of the Act and these rules and having regard to the advice of the Advisory Committee in this behalf, renew the certificate of registration, as specified in Form B, for a further period of five years from the date of expiry of the certificate of registration earlier granted.

(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 these rules, it shall, for reasons to be recorded in writing, reject the application for renewal of certificate of registration and communicate such rejection to the applicant as specified in Form C.

(4) The fees payable for renewal of certificate of registration shall be one half of the fees provided in sub-rule (1) of rule 5.

(5) On receipt of the renewed certificate of registration in duplicate or on receipt of communication of rejection of application for renewal, both copies of the earlier certificate of registration shall be surrendered immediately to the Appropriate Authority by the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic.

(6) In the event of failure of the Appropriate Authority to renew the certificate of registration or to communicate rejection of application for renewal of registration within a period of ninety days from the date of receipt of application for renewal of registration, the certificate of registration shall be deemed to have been renewed.

**9. Maintenance and preservation of records.**-<sup>7</sup>[(1) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres shall maintain a register showing, in serial order, the names and addresses of the men or women given genetic counselling, subjected to pre-natal diagnostic procedures or pre-natal diagnostic tests, the names of their spouse or father and the date on which they first reported for such counselling, procedure or test.]

(2) The record to be maintained by every Genetic Counselling Centre, in respect of each woman counseled shall be as specified in Form D.

<sup>8</sup>[(3) The record to be maintained by every Genetic Laboratory, in respect of each man or woman subjected to any pre-natal diagnostic procedure/technique/test, shall be as specified in Form E.]

<sup>9</sup>[(4) The record to be maintained by every Genetic Clinic, in respect of each man or woman subjected to any pre-natal diagnostic procedure/technique/test, shall be as specified in Form F.]

(5) The Appropriate Authority shall maintain a permanent record of applications for grant or renewal of certificate of registration as specified in Form H. Letters of intimation of every change of employee, place, address and equipment installed shall also be preserved as permanent records.

(6) 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 for a period of two years from the date of completion of counseling, 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.

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

<sup>4</sup>[(8) Every Genetic Counseling 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.]

**10. Conditions for conducting pre-natal diagnostic procedures.**-<sup>10</sup>[(1) Before conducting preimplantation genetic diagnosis, or any pre-natal diagnostic technique/test/procedure such as

amniocentesis, chorionic villi biopsy, foetoscopy, foetal skin or organ biopsy or cordocentesis, a written consent as specified in Form G, in a language the person undergoing such procedure understands, shall be obtained from her/him.]

Provided that where a Genetic Clinic has taken a sample of any body tissue or body fluid and sent it to a Genetic Laboratory for analysis or test, it shall not be necessary for the Genetic Laboratory to obtain a fresh consent in Form G.

<sup>11</sup>[(1A) Any person conducting ultrasonography/image scanning on a pregnant woman shall give a declaration on each report on ultrasonography/image scanning that he/she has neither detected nor disclosed the sex of foetus of the pregnant woman to any body. The pregnant woman shall before undergoing ultrasonography/image scanning declare that she does not want to know the sex of her foetus.]

(2) All the State Governments and Union Territories may issue translation of Form G in languages used in the State or Union Territory and where no official translation in a language understood by the pregnant woman is available, the Genetic Clinic may translate Form G into a language she understands.

<sup>11</sup>[11. Facilities for inspection.- (1) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre, nursing home, hospital, institute or any other place where any of the machines or equipments capable of performing any procedure, technique or test capable of pre-natal determination of sex or selection of sex before or after conception is used, shall afford all reasonable facilities for inspection of the place, equipment and records to the Appropriate Authority or to any other person authorised by the Appropriate Authority in this behalf for registration of such institutions, by whatever name called, under the Act, or for detection of misuse of such facilities or advertisement therefor or for selection of sex before or after conception or for detection/disclosure of sex of foetus or for detection of cases of violation of the provisions of the Act in any other manner.

(2) The Appropriate Authority or the officer authorized by it may seal and seize any ultrasound machine, scanner or any other equipment, capable of detecting sex of foetus, used by any organisation if the organisation has not got itself registered under the Act. These machines of the organisations may be released if such organisation pays penalty equal to five times of the registration fee to the Appropriate Authority concerned and gives an undertaking that it shall not undertake detection of sex of foetus or selection of sex before or after conception.]

<sup>12</sup>[12. Procedure for search and seizure. - (1) The Appropriate Authority or any officer authorised in this behalf may enter and search at all reasonable times any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Imaging Centre or Ultrasound Clinic in the presence of two or

more independent witnesses for the purposes of search and examination of any record, register, document, book, pamphlet, advertisement, or any other material object found therein and seal and seize the same if there is reason to believe that it may furnish evidence of commission of an offence punishable under the Act.

**Explanation:-** In these Rules -

- (1) 'Genetic Laboratory/Genetic Clinic/ Genetic Counselling Centre' would include an ultrasound centre/imaging centre/ nursing home/hospital/institute or any other place, by whatever name called, where any of the machines or equipments capable of selection of sex before or after conception or performing any procedure, technique or test for prenatal detection of sex of foetus, is used;
- (2) 'material object' would include records, machines and equipments; and
- (3) 'seize' and 'seizure' would include 'seal' and 'sealing' respectively. ]

(2) A list of any document, record, register, book, pamphlet, advertisement or any other material object found in the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic and seized shall be prepared in duplicate at the place of effecting the seizure. Both copies of such list shall be signed on every page by the Appropriate Authority or the officer authorized in this behalf and by the witnesses to the seizure:

Provided that the list may be prepared, in the presence of the witnesses, at a place other than the place of seizure if, for reasons to be recorded in writing, it is not practicable to make the list at the place of effecting the seizure.

(3) One copy of the list referred to in sub-rule (2) shall be handed over, under acknowledgement, to the person from whose custody the document, record, register, book, pamphlet, advertisement or any other material object have been seized:

Provided that a copy of the list of such document, record, register, book, pamphlet, advertisement or other material object seized may be delivered under acknowledgement, or sent by registered post to the owner or manager of the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, if no person acknowledging custody of the document, record, register, book, pamphlet, advertisement or other material object seized is available at the place of effecting the seizure.

(4) If any material object seized is perishable in nature, the Appropriate Authority, or the officer authorized in this behalf shall make arrangements promptly for sealing, identification and preservation of the material object and also convey it to a facility for analysis or test, if analysis or test be required:

Provided that the refrigerator or other equipment used by the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic for preserving such perishable material object may be sealed until such time as arrangements can be made for safe removal of such perishable material object and in such eventuality, mention of keeping the material object seized, on the premises of the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall be made in the list of seizure.

(5) In the case of non-completion of search and seizure operation, the Appropriate Authority or the officer authorized in this behalf may make arrangement, by way of mounting a guard or sealing of the premises of the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, for safe keeping, listing and removal of documents, records, book or any other material object to be seized, and to prevent any tampering with such documents, records, books or any other material object.

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**13. Intimation of changes in employees, place or equipment.** – Every Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall intimate every change of employee, place, address and equipment installed, to the Appropriate Authority within a period of thirty days of such change.

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**14. Conditions for analysis or test and pre-natal diagnostic procedures.** – (1) No Genetic Laboratory shall accept for analysis or test any sample, unless referred to it by a Genetic Clinic.

(2) Every pre-natal diagnostic procedure shall invariably be immediately preceded by locating the foetus and placenta through ultrasonography, and the pre-natal diagnostic procedure shall be done under direct ultrasonographic monitoring so as to prevent any damage to the foetus and placenta.

**15. Meetings of the Advisory Committees.**- The intervening period between any two meetings of Advisory Committees constituted under sub-section (5) of Section 17 to advise the Appropriate Authority shall not exceed sixty days.

**16. Allowances to members of the Central Supervisory Board.**- (1) The ex-officio members, and other Central and State Government officers appointed to the Board will be entitled to Travelling Allowance and Daily Allowance for attending the meetings of the Board as per the Travelling Allowance rules applicable to them.

(2) The non-official members appointed to, and Members of Parliament elected to the Board will be entitled to Travelling Allowance and Daily Allowance for attending the meetings of the Board as admissible to non-official and Members of Parliament as the case may be, under the Travelling Allowances rules of the Central Government.

**17. Public Information.**- (1) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres shall prominently display on its premises a notice in English and in the local language or languages for the information of the public, to effect that disclosure of the sex of the foetus is prohibited under law.

(2) At least one copy each of the Act and these rules shall be available on the premises of every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres, and shall be made available to the clientele on demand for perusal.

(3) The Appropriate Authority, the Central Government, the State Government, and the Government/Administration of the Union Territory may publish periodically lists of registered Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics and findings from the reports and other information in their possession, for the information of the public and for use by the experts in the field.

**4["18. Code of Conduct to be observed by persons working at Genetic Counseling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics. Imaging Centres etc.**

All persons including the owner, employee or any other persons associated with Genetic Counseling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics, Imaging Centres registered under the Act/these Rules shall -

- (i) not conduct or associate with, or help in carrying out detection or disclosure of sex of foetus in any manner;
- (ii) not employ or cause to be employed any person not possessing qualifications necessary for carrying out pre-natal diagnostic techniques/ procedures, techniques and tests including ultrasonography;
- (iii) not conduct or cause to be conducted or aid in conducting by himself or through any other person any techniques or procedure for selection of sex before or after conception or for detection of sex of foetus except for the purposes specified in sub-section (2) of section 4 of the Act;
- (iv) not conduct or cause to be conducted or aid in conducting by himself or through any other person any techniques or test or procedure under the Act at a place other than a place registered under the Act/these Rules;
- (v) ensure that no provision of the Act and these Rules are violated in any manner;
- (vi) ensure that the person, conducting any techniques, test or procedure leading to detection of sex of foetus for purposes not covered under section 4(2) of the Act or selection of sex before or after conception, is informed that such procedures lead to violation of the Act and these Rules which are punishable offences;
- (vii) help the law enforcing agencies in bring to book the violators of the provisions of the Act and these Rules;
- (viii) display his/her name and designation prominently on the dress worn by him/her;
- (ix) write his/her name and designation in full under his/her signature;
- (x) on no account conduct or allow/cause to be conducted female foeticide;
- (xi) not commit any other act of professional misconduct.

#### **19. Appeals.-**

- (1) Anybody aggrieved by the decision of the Appropriate Authority at sub-district level may appeal to the Appropriate Authority at district level within 30 days of the order of the sub-district level Appropriate Authority.

- (2) Anybody aggrieved by the decision of the Appropriate Authority at district level may appeal to the Appropriate Authority at State/UT level within 30 days of the order of the District level Appropriate Authority.
- (3) Each appeal shall be disposed of by the District Appropriate Authority or by the State/Union Territory Appropriate Authority, as the case may be, within 60 days of its receipt.
- (4) If an appeal is not made within the time as prescribed under sub-rule (1), (2) or (3), the Appropriate Authority under that sub-rule may condone the delay in case he/she is satisfied that appellant was prevented for sufficient cause from making such appeal.]

**THE PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE)  
(ADVISORY COMMITTEE) RULES, 1996**

In exercise of the powers conferred by Sec.32 of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994), the Central Government hereby makes the following rules, namely:-

**1. Short title and commencement.**

- (1) These rules may be called the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) (Advisory Committees) Rules, 1996.
- (2) They shall come into force on the date of their publication in the Official Gazette.

**2. Definitions.**

In these rules, unless the context otherwise requires:-

- (a) "Act" means the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994);
- (b) "Advisory Committee" means an Advisory Committee constituted under sub-section (5) of Section 17 of the Act;
- (c) "Chairman" means the Chairman of the Advisory Committee appointed under sub-section (5) of Section 17;
- (d) "Principle rules" means the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996;
- (e) "section" means a section of the Act;
- (f) "words and expressions" used herein and not defined in these rules but defined in the Act or in the principal rules, as the case may be, shall have the meanings, respectively, assigned to them in the Act or in the principle rules.

**3. Terms and conditions of appointment as a member of an Advisory Committee.**

- (1) No person shall be appointed as a member of an Advisory Committee if he –

- (a) has been convicted and sentenced to imprisonment for an offence which, in the opinion of the Central Government or the State Government, as the case may be, involves moral turpitude; or
- (b) is an undischarged insolvent; or
- (c) is of unsound mind and stands so declared by a competent Court; or
- (d) has been removed or dismissed from the service of the Government or a Corporation owned or controlled by the Government; or
- (e) has, in the opinion of the Central Government or the State Government, as the case may be, such financial or other interest as is likely to affect prejudicially the discharge by him of his functions as a member of the Advisory Committee; or
- (f) has, in the opinion of the Central Government or the State Government, as the case may be, been associated with the use or promotion of pre-natal diagnostic techniques for determination of sex.

(2) Every member of an Advisory Committee shall be a resident of the State or Union Territory, for which the Advisory Committee to which he is appointed as a member, has been constituted.

(3) A member of an Advisory Committee shall hold office during the pleasure of the Central Government or the State Government, as the case may be.

(4) Subject to the provisions of sub-rule (3), every such member shall hold office for a period not exceeding three years:

**Provided** that any person holding office as a member of an Advisory Committee immediately before the commencement of these rules shall hold such office only for the term of three years from the date of his appointment.

(5) A retiring member or a member whose term of office has expired by efflux of time shall be eligible for re-appointment.

(6) A casual vacancy in an Advisory Committee caused by the resignation, death, transfer or removal of any member or otherwise shall be filled by fresh appointment and the person so appointed shall hold office for a period not exceeding the term of office of the member in whose place he is appointed.

(7) The Central Government or the State Government, as the case may be, may remove from office any member of an Advisory Committee before the expiration of his term of office.

(8) Every member of an Advisory Committee shall be entitled to draw traveling and daily allowances for journeys performed by him for attending the meetings (including a meeting adjourned for want of quorum), of the Advisory Committee or for the purpose of discharging any other duties prescribed under the Act, or under the Principle rules or under these rules, on the scale admissible to First Grade Officers of the Government of the State or of the Union Territory, as the case may be.

#### **4. Meetings of the Advisory Committees.**

The intervening period between any two meetings of an Advisory Committee shall not exceed sixty days.

#### **5. Notice of meetings.**

(1) At least seven clear days' notice of all meetings of the Advisory Committee shall be given to each member, but an urgent meeting may be called by the Chairman at three clear days' notice:

**Provided that** if the Chairman is not available, and a meeting is required to be held within the time limit prescribed in Rule 4, the Appropriate Authority may call a meeting with seven clear days' notice after consultation with not less than four of the members of the Advisory Committee.

(2) The notice shall state the business to be transacted at the meeting and no business other than that stated shall be transacted at such meeting except with the consent of the Chairman or on his motion.

#### **6. Business ordinarily to be transacted at meetings.-** The business of the Advisory Committee shall ordinarily be transacted at a meeting duly called in accordance with the provisions of these rules:

**Provided that** the Chairman may, if he thinks fit, circulate any urgent matter among the members of the Advisory Committee for their opinion.

**7. Quorum.**- At every meeting of the Advisory Committee, four members shall form a quorum.

**8. Chairman of the meeting.**- Meetings of the Advisory Committee shall be presided over by the Chairman or in his absence, or if no Chairman has been appointed, by a member elected by the members present from among themselves,

**9. Assistance to be rendered by the Appropriate Authority to the Advisory Committee.**-

- (1) Every meeting of the Advisory Committee shall be attended by the Appropriate Authority concerned.
- (2) All secretarial and other assistance to the Advisory Committee for the discharge of its functions shall be provided by the Appropriate Authority.
- (3) The Appropriate Authority shall issue the notice of meeting, agenda, notes on agenda and the minutes of the meeting, in consultation with the Chairman, subject to the provisions of Rules 5,6, 7 and 12.

**10. Decisions on questions before the Advisory Committee.**

- (1) The advice tendered by the Advisory Committee shall be adopted, and in the event of any difference of opinion amongst the members, the matter shall be put to vote and decided by a simple majority of the members present.
- (2) The Appropriate Authority shall not have a right to vote.
- (3) In the event of tie in votes, the Chairman or in his absence, the member presiding shall have a second or casting vote.
- (4) The fact of any question having been decided by the process of voting instead of by adoption, shall be recorded in the minutes of that meeting of the Advisory Committee.

**11. Vacancies etc. not to invalidate proceedings of the Advisory Committees.**- No meeting or proceeding of the Advisory Committee shall be invalid merely by reason of-

- (a) any vacancy in, or any defect in the constitution of the Advisory Committee; or
- (b) any defect in the appointment of a person to be a member of the Advisory Committee; or

(c) any Irregularity in the procedure adopted by the Advisory Committee not affecting the merits of the case.

**12. Record of proceedings of the Advisory Committee.**- One set of the agenda, notes on agenda, supporting documents and minutes of every meeting of the Advisory Committee shall be authenticated by the signature of the Chairman or in his absence by the signature of the member presiding, and preserved by the Appropriate Authority as permanent records.

**PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX  
SELECTION) AMENDMENT RULES, 2014**

**PREAMBLE**

*In exercise of the powers conferred by section 32 of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994), the Central Government hereby makes the following rules further to amend the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996, namely:—*

1. (1) These rules may be called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Amendment Rules, 2014.  
(2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996, after rule 18, the following rule shall be inserted, namely:—

**18-A Code of Conduct to be observed by Appropriate Authorities.—**

- (1) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following general code of conduct, namely:-
  - (i) maintain dignity, and integrity at all times;
  - (ii) observe and implement the provisions of the Act and Rules in a balanced and standardised manner in the course of their work;
  - (iii) conduct their work in a just manner without any bias or a perceived presumption of guilt;
  - (iv) refrain from making any comments which demean individuals on the basis of gender, race, religion;
  - (v) delegate his or her powers by administrative order to any authorised officer in his or her absence and preserve the order of authorisation as documentary proof for further action.

(2) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following Conduct for Advisory Committees, namely:--

- (i) ensure that the re-constitution, functions and other relevant matters related to advisory committee shall be in accordance with the provisions of the Advisory Committee Rules, 1996;
- (ii) ensure that a person who is the part of investigating machinery in cases under the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994), shall not be nominated or appointed as a member of the Advisory Committee;
- (iii) ensure that the process of filling up of vacancies in Advisory Committee shall start at least ninety days before the probable date of the occurrence of vacancy;
- (iv) ensure that no person shall participate as a member or a legal expert of the Advisory Committee if he or she has conflict of interest;
- (v) conduct frequent meetings of the Advisory Committee to expedite the decisions regarding renewal, cancellation and suspension of registration.

(3) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for processing of complaint and investigation, namely:--

- (i) maintain appropriate diaries in support of registration of each of the complaint or case under the Act;
- (ii) attend to all complaints and maintain transparency in the follow-up action of the complaints;
- (iii) investigate all the complaints within twenty four hours of receipt of the complaint and complete the investigation within forty-eight hours of receipt of such compliant;
- (iv) as far as possible, not involve police for investigating cases under the Act as the cases under the Act are tried as complaint cases under the Code of Criminal Procedure, 1973 (2 of 1974).

(4) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for registration and renewal of applications under the Act, namely:--

- (i) dispose of the application for renewal and new registration within a period of seventy days from the date of receipt of application;
- (ii) ensure that no application for fresh registration or renewal is accepted if any case is pending in any court against the applicant.

(5) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for Legal Action, namely:--

- (i) ensure that protection and expenses of witness shall be met from the registration amount collected;
- (ii) ensure that all the notifications of the Government be produced in original in the court and a copy of the same be preserved;
- (iii) ensure that while filing the cases, all the papers, records, statements, evidence, panchnama and other material objects attached to the case file shall be in original;
- (iv) suspend the certificate of registration in the course of taking legal action of seizure and sealing of the facility;
- (v) ensure that there shall be no violation of the provisions of the Medical Termination Pregnancy Act, 1971 (34 of 1971) and the Rules made there-under while implementing the provisions of the Pre-conception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996;
- (vi) take immediate action for filing appeal, revision or other proceeding in higher courts in case of order of acquittal within a period of thirty days but not later than fifteen days of receipt of the order of acquittal.

(6) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall submit quarterly progress report to the Government of India through State Government and maintain Form H for keeping the information of all the registrations made readily available.

(7) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following regulation of ultrasound equipments, namely:--

- (i) monitor the sales and import of ultrasound machines including portable or buyback, assembled, gift, scrap or demo;
- (ii) ensue regular quarterly reports from ultrasound manufacturers, dealers, wholesalers and retailers and any person dealing with the sales of ultrasound machines at the State level;
- (iii) conduct periodical survey and audit of all the ultrasound machines sold and operating in the State or district to identify the unregistered machines;
- (iv) file complaint against any owner of the unregistered ultrasound machine and against the seller of the unregistered ultrasound machine.

(8) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for inspection and monitoring, namely:—

- (i) conduct regular inspection of all the registered facilities once in every ninety days and shall preserve the inspection report as documentary evidence and a copy of the same be handed over to the owner of facility inspected and obtain acknowledgement in respect of the inspection;
- (ii) place all the inspection reports once in three months before the Advisory Committee for follow up action;
- (iii) maintain bimonthly progress report containing number of cases filed and persons convicted, registration made, suspended or cancelled, medical licenses cancelled, suspended, inspections conducted, Advisory Committee meetings held at the district level and quarterly progress report at the State level;
- (iv) (a) procure the copy of the charges framed within seven days and in the case of doctors, the details of the charges framed shall be submitted within seven days of the receipt of copy of charges framed to the State Medical Council;

(b) procure the certified copy of the order of conviction as soon as possible and in the case of conviction of the doctors, the certified copy of the order of conviction shall be submitted within seven days of the receipt of copy of the order of conviction.

(9) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for accountability, namely:—

- (i) obtain prior sanction or approval of the Government of India for any resolution concerning the implementation of the provisions of the Act;
- (ii) take action, if any, required under the Act and immediately on receipt of notice under clause (b) of sub-section (1) of section 28 of the Act and if he or she fails to do so, shall not be entitled for the protection under section 31 of the said Act and defend the case in his or her own capacity and at his or her own cost.

(10) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall follow the following financial guidance, namely:—

- (i) maintain a separate and independent bank account operated by two officers jointly, at all levels;
- (ii) ensure transparency and adherence to standard Government financial norms for disbursement of money.

**PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES  
(PROHIBITION OF SEX SELECTION) AMENDMENT RULES, 2015**

**PREAMBLE**

*In exercise of the powers conferred by Section 32 of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994), the Central Government hereby makes the following rules further to amend the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996, namely:--*

**1.** (1) These rules may be called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Amendment Rules, 2015.

(2) They shall come into force on the date of their publication in the Official Gazette.

**2.** In the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996, rule 18-A, sub-rule (4) in clause (ii), the following shall be substituted, namely:--

"(ii) ensure that no application for fresh registration or renewal of registration is accepted if any case is pending in any court against the applicant for violation of any provision of the Act and the rules made thereunder".

**LANDMARK JUDGMENTS**

- The Supreme Court of India in '*Voluntary Health Association of Punjab V Union of India and Ors.*' (2013)4SCC1 laid down directions so as to supervise and oversee how effective is the implementation of the P.N. & P.N.D.T. Act. Besides the said directions the Hon'ble court held that Actions shall be taken in place, where woman are not treated with proper respect and dignity in society.
- The Supreme Court Of India in '*Center for Enquiry into Health and Allied Themes (CEHAT) & Ors. V Union of India and Ors.*' (2001)5SCC577 noticed the misuse of the Act and gave various directions for its proper implementation. Categorical directions were issued to the Central Govt., Central Supervisory Board(CSB), State Governments/UT Administrations and appropriate authorities.
- *The Supreme Court again in 'Centre for Enquiry into Health and Allied Themes v. Union of India' (2003) 8 SCC 398* gave various other directions for the implementation of the P.N. & P.N.D.T. Act