

(2) The provisions of the Code of Criminal Procedure, 1973 (2 of 1974) relating to searches and seizures shall, so far as may be, apply to every search or seizure made under this Act.

### 31. Protection of action taken in good faith

No suit, prosecution or other legal proceeding shall lie against the Central or the State Government or the Appropriate Authority or any officer authorized by the Central or State Government or by the Authority for anything which is in good faith done or intended to be done in pursuance of the provisions of this Act.

#### <sup>1</sup>[31A. Removal of difficulties

(1) If any difficulty arises in giving effect to the provisions of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002, the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of the said Act as appear to it to be necessary or expedient for removing the difficulty:

PROVIDED that no order shall be made under this section after the expiry of a period of three years from the date of commencement of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002.

### 32. Power to make rules

(1) The Central Government may make rules for carrying out the provisions of this Act.

(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for-

- <sup>1</sup>[(i) the minimum qualifications for persons employed at a registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic under clause (2) of section 3;
- (ia) the manner in which the person conducting ultrasonography on a pregnant woman shall keep record thereof in the clinic under the proviso to sub-section (3) of section 4;
- (iii) The form in which consent of a pregnant woman has to be obtained under section 5;
- (iv) The procedure to be followed by the members of the Central Supervisory Board in the discharge of their functions under sub-section (4) of section 8;
- (v) Allowances for members other than ex officio members admissible under sub-section (5) of section 9;
- <sup>1</sup>[(iva) code of conduct to be observed by persons working at Genetic Counselling Centre, Genetic Laboratories and Genetic Clinic to be laid down by the Central Supervisory Board under clause (iv) of section 16;
- (ivb) the manner in which reports shall be furnished by the State and Union Territory Supervisory Boards to the Board and the Central Government in respect of various activities undertaken in the State under the Act under clause (iv) of sub-section (1) of section 16A;
- (ivc) empowering the Appropriate Authority in any other matter under clause (d) of section 17A;]

1. Inserted by Act 14 of 2003, w.e.f. 14-2-2003 vide SO 175(E), dt. 14-2-2003

### 21. Appeal

The Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic may, within thirty days from the date of receipt of the order of suspension or cancellation of registration passed by the Appropriate Authority under section 20, prefer an appeal against such order to-

- (i) the Central Government, whether the appeal is against the order of the Central Appropriate Authority; and
- (ii) the State Government, where the appeal is against the order of the State Appropriate Authority in the prescribed manner.

#### CHAPTER VII

#### OFFENCES AND PENALTIES

### <sup>1</sup>[22. Prohibition of advertisement relating to pre-conception and pre-natal determination of sex and punishment for contravention

(1) No person, organization, Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic including clinic, Laboratory or Centre having ultrasound machine or imaging machine or scanner or any other technology capable of undertaking determination of sex of foetus or sex selection shall issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement, in any form, including internet, regarding facilities of pre-natal determination of sex or sex selection before conception available at such Centre, Laboratory, Clinic or at any other place.

(2) No person or organization including Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement in any manner regarding pre-natal determination or pre-conception selection of sex by any means whatsoever, scientific or otherwise.

(3) Any person who contravenes the provision 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 any other document including advertisement through internet or any other media in electronic or print form and also includes any visible representation made by means of any hoarding, wall-painting, signal, light, sound, smoke or gas.]

### 23. Offences and penalties

(1) Any medical geneticist, gynaecologist, registered medical practitioner or any person who owns Genetic Counselling Centre, a Genetic Laboratory or a Genetic Clinic or is employed in 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

1. Substituted vide Act 14 of 2003, w.e.f. 14-2-2003 vide SO 175(E), dt. 14-2-2003

case is disposed and on conviction for removal of his name from the register of the Council for a period of five year 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, sinologist or imaging specialist or registered medical practitioner or any other person for sex selection or for conducting pre-natal diagnostic techniques on any pregnant women for the purpose 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.]

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

Notwithstanding anything contained in the Indian Evidence Act, 1872 (1 of 1872), the court shall presume unless the contrary is proved that the pregnant women was compelled by her husband or any other relative, as the case may be, to undergo pre-natal diagnostic technique for the purposes other than those specified in sub-section (2) of section 4 and such person shall be liable for abatement of offence under sub-section (3) of section 23 and shall be punishable for the offence specified under that section.]

**25. Penalty for contravention of the provisions of the Act or rules for which no specific punishment is provided**

Whoever contravenes any of the provisions of this Act or any rules made thereunder for which no penalty has been elsewhere provided in this Act, shall be punishable with imprisonment for a term which may extend to three months or with fine, which may extend to one thousand rupees or with both and in the case of continuing contravention with an additional fine which may extend to five hundred rupees for every day during which such contravention continues after conviction for the first such contravention.

**26. Offences by companies**

(1) Where any offence, punishable under this Act has been committed by a company every person who, at the time the offence was committed was in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

PROVIDED that nothing contained in this sub-section shall render any such person liable to any punishment, if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where any offence punishable under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation : For the purpose of this section,-

1. Substituted by Act 14 of 2003, w.e.f. 14-2-2003 vide SO 175(E), dt. 14-2-2003

(a) "company" means any body corporate and includes a firm or other association of individuals, and

(b) "director", in relation to a firm means a partner in the firm.

**27. Offence to be cognizable, non-bailable and not-compoundable**

Every offence under this Act shall be cognizable, non-bailable and non-compoundable

**28. Cognizance of offences**

(1) No court shall take cognizance of an offence under this Act except on a complaint made by-

(a) the Appropriate Authority concerned, or any officer authorized in this behalf by the Central Government or State Government, as the case may be, or the Appropriate Authority; or

(b) a person who has given notice of not less than <sup>1</sup>[fifteen days] in the manner prescribed, to the Appropriate Authority, of the alleged offence and of his intention to make a complaint to the court.

*Explanation:* For the purpose of this clause, "person" includes a social organization.

(2) No court other than that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

(3) Where a complaint has been made under clause (b) of sub-section (1), the court may, on demand by such person, direct the Appropriate Authority to make available copies of the relevant records in its possession to such person.

**CHAPTER VIII  
MISCELLANEOUS**

**29. Maintenance of records**

(1) All records, charts, forms, reports, consent letters and all the documents required to be maintained under this Act and the rules shall be preserved for a period of two years or for such period as may be prescribed;

PROVIDED that, if any criminal or other proceedings are instituted against any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, the records and all other documents of such Centre, Laboratory or clinic shall be preserved till the final disposal of such proceedings.

(2) All such records shall, at all reasonable times, be made available for inspection to the Appropriate Authority or to any other person authorized by the Appropriate Authority in this behalf.

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

<sup>2</sup>[(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, Genetic Clinic or any other place, such Authority or any officer authorized 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, Genetic Clinic or any other place and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize and seal 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.]

1. Substituted for "thirty days" by Act 14 of 2003, w.e.f. 14-2-2003 vide SO 175(E), dt. 14-2-2003

2. Substituted, *ibid*.

- (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 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) Micro centrifuge.
  - (8) Electrophoresis apparatus and power supply.
  - (9) Vertex mixer.
  - (10) Magnetic stirrer.
  - (11) pH meter
  - (12) A sensitive balance (preferably electronic) with sensitivity of milligram.
  - (13) Double distillation apparatus (glass).
  - (14) P.C.R. machine.
  - (15) Refrigerator centrifuge.

- (v) the period intervening between any two meetings of the Advisory Committee under the proviso to sub-section (8) of section 17;
- (vi) the terms and conditions subject to which a person may be appointed to the Advisory Committee and the procedure to be followed by such Committee under sub-section (9) of section 17;
- (vii) the form and manner in which and application shall be made for registration and the fee payable thereof under sub-section (2) of section 18;
- (viii) the facilities to be provided, equipment and other standards to be maintained by the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic under sub-section (5) of section 18;
- (ix) the form in which a certificate of registration shall be issued under sub-section (1) of section 19;
- (x) the manner in which and the period after which a certificate of registration shall be renewed and the fee payable for such renewal under sub-section (3) of section 19;
- (xi) the manner in which an appeal may be preferred under section 21;
- (xii) the period up to which records, charts etc, shall be preserved under sub-section (1) of section 29;
- (xiii) the manner in which the seizure of documents, records, objects, etc., shall be made and the manner in which seizure list shall be prepared and delivered to the person from whose custody such documents, records or objects were seized under sub-section (1) of section 30;
- (xiv) any other matter that is required to be, or may be, prescribed.

### 33. Power to make regulation

The Board may, with 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 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.

### 34. Rules and regulations to be laid before Parliament

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 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.

# THE PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION) RULES, 1996

[GSR 1 (E), dt. 1-1-1996]

[As amended vide GSR 418(E), dt 4-6-2012, w.e.f. 5-6-2012]

In exercise of the powers conferred by section 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

<sup>1</sup>[(1) These Rules may be called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rule, 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);<sup>2</sup>

(b) "employee" means a person working in or employed by a<sup>3</sup>[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres,] and includes those working on part-time, contractual, consultancy, honorary or on any other basis;

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

<sup>4</sup>[(d) xxx]

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

(f) words and expression 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>5</sup>[(g) "Mobile Medical Unit" means a mobile vehicle which provides specialized facilities for the patients, requiring basic specialist services and

1. Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. Prior to substitution sub-rule (1) stood as under "(1) These rule may be called the Pre-natal Diagnostic Techniques (Regulation and prevention of Misuse Rules, 1996."

2. Now "The Pre-natal Diagnostic Techniques (Provision of Sex Selection) Act, 1994 (.....) of 1994."

3. Substituted for "Genetic Counselling Centre, Genetic Laboratory and Genetic clinic", ibid.

4. Omitted, ibid. Prior to omission clause (d) stood as under: "(d) "Schedule" means a Schedule appended to these rules"

5. Inserted vide GSR 80 (E), dt. 7-2-2012, w.e.f. 9-2-2012

Provided improved access to health facilities and equitable distribution of health services at the doorsteps, across the country especially in the underserved areas.

(h) "Mobile Genetic Clinic" means a mobile medical unit 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.]

## <sup>1</sup>[3. Minimum requirements

The qualifications of the employees, the requirement of equipment. 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 geneticists,

having adequate space and educational charts/models/equipments for carrying out genetic counseling may set up a genetic counselling centre 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 Science or a degree or diploma in medical laboratory course with at least one year experience in conducting appropriate pre-natal diagnostic techniques, test 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

1. Substituted vide GSR 109 (E), dt. 14-2-2003, w.e.f. 14-2-2003

As part of a medical mobile unit and such a vehicle has to be registered as a mobile genetic unit.]

(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.

#### <sup>1</sup>5. Application Fee

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

- (a) <sup>2</sup>[Rupees Twenty-five thousand] for Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre.
- (b) <sup>3</sup>[Rupees thirty-five thousand] for an institute, hospital, nursing home, or 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 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 <sup>4</sup>[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres] 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.

1. Substituted vide GSR 109(E), dt 14-2-2003, w.e.f. 14-2-2003

2. Substituted for "Rs. 3,000.00" vide GSR 418(E), dt 4-6-2012, w.e.f. 5-6-2012.

3. Substituted for "Rs.4,000.00", ibid.

4. Substituted for "Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic" vide GSR 109(E), 14-2-2003, w.e.f. 14-2-2003.

(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 Sinologist, 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 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.
- (h) Genetic Works Station.]

<sup>1</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.]

#### <sup>2</sup>[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.

1. Inserted vide GSR 418(E), dt. 4-6-2012, w.e.f. 5-6-2012

2. Inserted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003

(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 machine/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.]

### **<sup>1</sup>[3B. Regulation of portable machines**

(1) The use of portable ultrasound machine or any other portable machine or device which has the potential for selection of sex before conception or detection of sex during pregnancy shall be permitted only in the following conditions, namely:-

- (a) The portable machine being used, within the premises it is registered, for providing services to the indoor patients;
- (b) A part of a mobile unit, offering a bouquet of other health and medical services.

*Explanation :* For the purpose of this sub-rule, the expression “other health and medical services” means the host of services provided by the mobile medical unit which may include the following, namely:-

#### **(i) Curative**

- (a) Referral of complicated cases;
- (b) Early detection of TB, Malaria, Leprosy, Kala-Azar and other locally endemic communicable diseases and non-communicable disease such as hypertension diabetes, cataract cases etc;
- (c) Minor surgical procedures and suturing;
- (d) Specialist services such as O and G Specialist, Paediatrician and Physician;

#### **(ii) Reproductive and Child Health Services**

- (a) Ante natal check up and related services;
- (b) Referral for complicated pregnancies;
- (c) Promotion of institutional deliveries;
- (d) Post-natal check up;
- (e) Immunization clinics;
- (f) Treatment of common childhood illness;
- (g) Treatment of Reproductive Tract Infection or Sexually Transmitted Infections;
- (h) Adolescents care such as lifestyle education, counselling, treatment of minor ailments.

1. Inserted vide GSR 80(E), dt.7-2-2012, w.e.f. 9-2-2012

#### **(iii) Family Planning Services**

- (a) Counselling for spacing and permanent method;
- (b) Distribution of contraceptives

#### **(iv) Diagnostic**

- (a) Investigation facilities like haemoglobin, urine examination;
- (b) Clinical detection of leprosy tuberculosis or endemic disease;
- (c) Screening of cancer etc.

#### **(v) Specialised facilities and services**

- (a) X-ray;
- (b) ECG;
- (c) Ultrasound test.

#### **(vi) Emergency services and care in items of disaster or epidemic or public health emergency or accidents etc.**

### **(2) Regulation of services to be offered by Mobile Genetic Clinic**

- (a) A Mobile Genetic Clinic shall operate and offer pre-natal diagnostic techniques, only as part of a Mobile Medical Unit offering a bouquet of other health and medical services, in urban slums or rural or remote or hilly or hard to reach areas for improved access to health care services by underserved populations.
- (b) The machine under no circumstances shall be used for sex determination of the foetus.
- (c) The stand alone mobile ultrasound clinic offering only pre-natal diagnostic facilities are prohibited.
- (d) The mobile medical unit offering diagnostic services shall have adequate space for providing the facilities to patients.]

### **4. Registration of <sup>1</sup>[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres]**

<sup>2</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;
- (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; and]

<sup>3</sup>[(iii) The registration of a genetic clinic shall also include the registration of each and every mobile genetic clinic offering pre-natal diagnostic facilities

1. Substituted for “Genetic Counselling, Genetic Laboratory and Genetic Clinic” vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003.

2. Substituted vide GSR 109(E), dt 14-2-2003, w.e.f. 14-2-2003. Prior to substitution sub-rule (1) stood as under “(1) An application or registration shall be made to the Appropriate Authority, in duplicate, in Form A”

3. Inserted vide GSR 80(E), dt. 7-2-2012, w.e.f. 9-2-2012

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 therefor or for selection of sex before or after conception or for detection/disclosure of sex of foetus or for detection of causes of violation of the provisions of the Act in any other manner.

<sup>1</sup>[(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 such organizations shall be confiscated and further action shall be taken as per the provisions of section 23 of the Act.]

## 12. Procedure for search and seizure

<sup>2</sup>[(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 rule-

- (1) 'Genetic Laboratory/Genetic Clinic/Genetic Counselling Centre' would include an ultrasound centre / imaging centre/nursing home/hospital/institute or any other place, by whatsoever 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 pre-natal detection of sex of foetus is used;
- (2) 'material object' would include record, 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 <sup>3</sup>[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres] 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.

1. Substituted vide GSR 426(E), dt. 31-5-2011, w.e.f. 2-6-2011. Prior to substitution, sub-section (2) read and under:

"(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 of selection of sex before or after conception."

2. Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003.

3. Substituted for "Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic", ibid.

diagnostic test or procedures, depending on the availability of place, equipment and qualified employees, and standards maintained by such laboratory or clinic.

- <sup>1</sup>[(2A)(a) One copy of the certificate of registration shall be displayed by the registered mobile medical unit inside the vehicle at a conspicuous place.
- (b) The certificate of registration for such unit, shall clearly specify the following-
- (I) the area of its operation, which shall not exceed the district wherein it is registered;
  - (II) the number of portable machines installed and being used in the vehicle;
  - (III) the make and model number of the portable machine;
  - (IV) the registration number of the vehicle;
  - (iv) Full address of the service provider for the mobile medical unit.

(2B) The portable equipment used for conducting pre-natal diagnostic test shall be an integral part of the mobile medical unit and such equipment shall not be used outside such unit under any circumstances.

(2C) In case of a breakdown of the vehicle or for any other reason due to which the registered unit cannot be used as a Genetic Clinic, the Appropriate Authority has to be informed within a period of seven days.]

(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 <sup>2</sup>[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres] 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 or 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 <sup>2</sup>[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres] 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 <sup>2</sup>[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres], 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.

1. Inserted vide GSR 80(E), dt. 7-2-2012, w.e.f. 9-2-2012

2. Substituted for "Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic" vide GSR 109 (E), dt. 14-2-2003, w.e.f. 14-2-2003.

**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 <sup>1</sup>[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres].

(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>2</sup>[(1) Every Genetic Counselling Centre, Genetic Laboratory, <sup>3</sup>[Genetic Clinic including a Mobile 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 test, the names of their spouse or farther 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>2</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.

(4) The record to be maintained by every <sup>3</sup>[Genetic Clinic including a Mobile 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.

1. Substituted for "Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic" vide GSR 109(E), 14-2-2003, w.e.f. 14-2-2003.

2. Substituted, *ibid*.

3. Substituted for "Genetic Clinic" vide GSR 90 (E), 7-2-2012, w.e.f. 9-2-2012.

(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 Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres] for a period of two years from the date of completion of counselling pre-natal diagnostic procedure or pre-natal diagnostic test, as the case may be. In the event of any legal proceedings, the records shall be preserved till the final disposal of legal proceedings, or till the expiry of the said period of two years, whichever is later.

(7) In case the <sup>1</sup>[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres] maintain 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>2</sup>[(8) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres shall send a complete report in respect of all pre-conception or pregnancy related procedures/techniques/tests conducted by them in respect of each month by 5<sup>th</sup> day of the following month to the concerned Appropriate Authority.]

**10. Conditions for conducting pre-natal diagnostic procedures**

<sup>3</sup>[(1) Before conducting pre implantation genetic diagnosis, or any pre-natal diagnostic technique/test/procedure such as amniocentesis, chorionic vill biopsy, foetuscopy, 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>2</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>3</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

1. Substituted for "Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic" vide GSR 109(e), dt. 14-2-2003, w.e.f. 14-2-2003.

2. Inserted, *ibid*.

3. Substituted, *ibid*.



- (3) *Paediatrician with 6 months' experience in genetic counseling, or having completed 4 weeks' training in genetic counseling.*

### SCHEDULE II

[Refer rule 3(1)]

#### REQUIREMENTS FOR REGISTRATION OF A GENETIC LABORATORY

##### A. PLACE

*A room with adequate space for carrying out test.*

##### B. EQUIPMENT

*These are categorized separately for each of the under-mentioned studies.*  
*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 (preferable electronic) with sensitivity of 0.1 milligram*
- (14) *Double distillation apparatus (glass).*

##### *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 mixture*
- (13) *Magnetic stirrer*
- (14) *pH meter*

(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 seize may be delivered under acknowledgement, or sent by registered post to the owner or manager of the <sup>1</sup>[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres], if no person acknowledging custody of the document, record, register, book, pamphlet, advertisement or other material object seize 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 required:

PROVIDED that the refrigerator or other equipment used by the <sup>1</sup>[Genetic Counselling Centre, Genetic Clinic, Ultrasound Clinic and Imaging Centres] 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 <sup>1</sup>[Genetic Counselling Centre, Genetic Clinic, Ultrasound Clinic and Imaging Centres] 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 arrangements, by way of mounting a guard or sealing of the premises of the <sup>1</sup>[Genetic Counselling Centre, Genetic Clinic, Ultrasound Clinic and Imaging Centres] 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 <sup>1</sup>[Genetic Counselling Centre, Genetic Clinic, Ultrasound Clinic and Imaging Centres] shall intimate every change of employee, place, address and equipment installed, to the Appropriate Authority <sup>2</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 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.

1. Substituted for "Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic" vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003.

2. Substituted for "within a period of thirty days of such change" vide GSR 418(E), dt. 4-6-2012, w.e.f. 5-6-2012.

**15. Meeting of the Advisory Committee**

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 Allowances 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 <sup>1</sup>[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 languages for the information of the public to the 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 <sup>1</sup>[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 <sup>1</sup>[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic Ultrasound clinic 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.

<sup>2</sup>[18. Code of Conduct to be observed by persons working at Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinic 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 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;

1. Substituted for "Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic" vide GSR 109(E) 14-2-2003, w.e.f. 14-2-2003.

2. Inserted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003.

- (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 bringing 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) on no account conduct or allow/cause to be conducted female foeticide;
- (x) not commit any other act of professional misconduct.]

**<sup>1</sup>[19. Appeals**

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

**<sup>2</sup>[SCHEDULE]**

[Refer rule 3(1)]

**REQUIREMENTS FOR REGISTRATION OF A GENETIC COUNSELLING CENTRE****A. PLACE**

*A room with an area of seven (7) square metres.*

**B. EQUIPMENT**

*Educational charts/models.*

**C. EMPLOYEES**

*Any one of the following:-*

- (1) *Medical Geneticist.*
- (2) *Gynaecologist with 6 months' experience, in genetic counseling, or having completed 4 weeks' training in genetic counseling.*

1. Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003.

2. Italicized Schedules, I, II, and III omitted, Ibid.

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

Date: \_\_\_\_\_  
 Place: \_\_\_\_\_ (.....)  
 Name, designation and signature of the person authorized to sign on behalf of the organisation to be registered

[SEAL OF THE ORGANISATION SOUGHT TO BE REGISTERED]

**ACKNOWLEDGEMENT**  
 [Refer rule 4(2) and 8(1)]

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

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

OR

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

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

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

Date: \_\_\_\_\_  
 Place: \_\_\_\_\_ SEAL]

**[FORM B]**  
 [Refer rules 6(2), 6(5) and 8(2)]  
**CERTIFICATE OF REGISTRATION**  
 (To be issued in duplicate)

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

1. Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003.

- (15) A sensitive balance (preferable electronic) with sensitivity of 0.1 milligram.
- (16) Double distillation apparatus (glass)
- (17) Liquid nitrogen tank.

**Molecular studies:**

- (1) Inverted microscope.
- (2) Incubator
- (3) Oven
- (4) Autoclave.
- (5) Refrigerators (4degree and minus 20 degree Centigrade)
- (6) Water bath.
- (7) Micro centrifuge.
- (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

**C. EMPLOYEES:**

- (1) A Medical Geneticist
- (2) A laboratory technician having a B. Sc. Degree in Biological Science or a degree or a diploma in medical laboratory course with at least one year's experience in conducting appropriate pre-natal diagnostic tests.

**SCHEDULE III**  
 [Refer rule 3(1)]

**REQUIREMENTS FOR REGISTRATION OF A GENETIC CLINIC**

**A. PLACE**

A room with an area of twenty (20) square meter with appropriate aseptic arrangements.

**B. EQUIPMENT**

- (1) Equipment and accessories necessary for carrying out clinical examination by an obstetrician/gynaecologist.
- (2) Equipment, accessories, necessary for other facilities required for operations envisaged in the Act.

- \*(a) An ultra-sonography machine
  - \*(b) Appropriate catheter and equipment for carrying out chorionic villi aspirations per vagina or per abdomen.
  - \*(c) Appropriate sterile needle for amniocentesis or cordocentesis.
  - \*(d) A suitable foetoscope with and appropriate accessories for foetoscopy, foetal skin or organ biopsy or foetal blood sampling shall be optional.
- (3) Equipment for dry and wet sterilization.

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

C. EMPLOYEES

(1) A Gynaecologist with adequate experience in pre-natal diagnostic procedures (should have performed at least 20 procedures under supervision of a Gynaecologist experienced in the procedure which is going to be carried out, for example chorionic villi biopsy, amniocentesis, cordocentesis and others as indicated at B above).

(2) A Radiologist or Registered Medical Practitioner for carrying out ultrasonography. The required experience shall be 100 cases under supervision of similarly qualified person experienced in these techniques.

\* These constitute the minimum requirement of equipment for conducting the relevant procedure.]

[FORM A

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

(To be submitted in Duplicate with supporting documents as enclosures)  
APPLICATION FOR REGISTRATION OR RENEWAL OF  
REGISTRATION OF A GENETIC COUNSELLING CENTRE/ GENETIC  
LABORATORY/ GENETIC CLINIC/ ULTRASOUND CLINIC/  
IMAGING CENTRE

- 1. Name of the applicant  
(Indicate name of the organization sought to be registered)
  - 2. Address of the applicant
  - 3. Type of facility to be registered  
(Please specify whether the application is for registration of a Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic / Ultrasound Clinic / Imaging Centre or any combination of these.)
  - 4. Full name and address / address of Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic / Ultrasound Clinic / Imaging Centre with Telephone/Fax number(s) /Telegraphic /Telex/E-mail address(es).
  - 5. Type of ownership of Organisation (individual ownership/ partnership/company/co-operative/any other to be specified). In case type of organization is other than individual ownership, furnish copy of articles of association and names and address of other persons responsible for management, as enclosure.
  - 6. Type of Institution (Govt. Hospital/Municipal Hospital/Public Hospital/Private Hospital/Private Nursing Home/ Private Clinic/ Private Laboratory/any other to be stated).
  - 7. Specific pre-natal diagnostic procedures/tests for which approval is sought.
    - (a) Invasive          (i) amniocentesis/chrionic villi aspiration/  
                                chromosomal/biochemical/molecular studies.
    - (b) Non-Invasive Ultrasonography
- Leave blank if registration is sought for Genetic Counselling Centre only.

1. Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003.

- 8. Equipment available with the make and model of each equipment (List to be attached on a separate sheet).
- 9. (a) Facilities available in the Counselling Centre  
(b)whether facilities are or would be available in the Laboratory/ clinic for the following tests:
  - (i) Ultrasound
  - (ii) Amniocentesis
  - (iii) Chorionic villi aspiration
  - (iv) foetoscopy
  - (v) foetal biopsy
  - (vi) Cordocentesis

Whether facilities are available in the Laboratory /Clinic for the following:

- 10. Names, qualifications, experience and registration number of employees (may be furnished as an enclosure)
- 11. State whether the Genetic Counselling Centre/Genetic Laboratory/ Genetic Clinic / Ultrasound Clinic / Imaging Centre<sup>1</sup> qualifies for registration in terms of requirements laid down in rule 3.
- 12. For renewal applications only:
  - (a) Registration No.
  - (b) Date of issue and date of expiry of existing certificate of registration.
- 13. List of Enclosures;  
(Please attach a list of enclosure /supporting documents attached to this application.)

Date :

Place: (.....)  
Name, designation and signature of the person  
Authorized to sign on behalf of the organization  
To be registered.

DECLARATION

I, Sh./Smt/Kum./Dr. ....son/daughter/ wife of ..... aged ..... years resident of ..... Working as (indicate designation) ..... in (indicate name of the organization to the registered) ..... hereby declare that I have read and understood the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994)<sup>2</sup> and the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996.<sup>3</sup>

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- 1. Strike out whichever is not applicable or not necessary. All enclosure are to be authenticated by signature of the applicant.
- 2. Read as "The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994)"
- 3. Read as "The Pre-concept and Pre-natal Diagnostic (Prohibition of Sex Selection) Rules, 1996"

- (vi) Sex linked disorder
- (vii) Single genedisorder
- (viii) Any other (specify)
- B. Advance maternal age (35 years or above)
- C. Mother /father/sibling having genetic disease (specify)
- 10. Laboratory test carried out (give details)
  - (i) Chromosomal studies
  - (ii) Biochemical studies
  - (iii) Molecular studies
  - (iv) Preimplantation genetic diagnosis
- 11. Result of diagnosis  
If abnormal give details Normal/ Abnormal
- 12. Date(s) on which tests carried out.  
The results of the Pre-natal diagnostic test were conveyed to .....  
on.....

Place: \_\_\_\_\_ Name, Signature and Registration No of the  
Date:] \_\_\_\_\_ Medical Geneticist/Director of the Institute

**FORM F**

[Refer proviso to section 4(3), rules 9(4) and 10(1A)]

(New amended on 4<sup>th</sup> February, 2014 notified on 31<sup>th</sup> January, 2014)

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

**Section A : To be filled in for all diagnostic Procedures/Tests**

1. Name and complete address of Genetic Clinic /Ultrasound Clinic Imaging centre: \_\_\_\_\_
2. Registration No. (Under PC & PNDT Act, 1994) \_\_\_\_\_
3. Patient's Name : \_\_\_\_\_ Age: \_\_\_\_\_
4. Total Number of living children : \_\_\_\_\_
  - (a) Number of living Sons with age of each living son (in years or months): \_\_\_\_\_
  - (b) Number of living Daughter with age of each living daughter (in years or months) : \_\_\_\_\_
5. \_\_\_\_\_
6. Husband's/Wife's/Father's/Mother's Name : \_\_\_\_\_
7. Full postal address of the patient with contact Number, if any: \_\_\_\_\_
7. (a) Referred by (full name and address of Doctor(s) Genetic Counselling Centre) : \_\_\_\_\_

2. Read as "The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act. 1994 (57 of 1994)"
  2. This registration is granted subject to the aforesaid Act and Rules thereunder and any contravention thereof shall result in suspension or cancellation of this Certificate of Registration before the expiry of the said period of five years apart from prosecution.
    - A. Name and address of the Genetic Counselling Centre\*/Genetic Laboratory\*/Genetic Clinic\*/Ultrasound Clinic\*/Imaging Centre\*
    - B. Pre-natal diagnostic procedures\* approved for (Genetic Clinic)
      - Non-Invasive
        - (j) Ultrasound
      - Invasive
        - (ii) Amniocentesis
        - (iv) Chorionic villi biopsy
        - (v) Foetoscopy
        - (vi) Foetal skin r organ biopsy
        - (vii) Cordocentesis
        - (viii) Any other (specify)
    - C. Pre-natal diagnostic test\* approved (for Genetic Laboratory)
      - (i) Chromosomal studies
      - (ii) Biochemical studies
      - (iii) Molecular studies
    - D. Any other purpose (please specify)
  3. Model and make of equipments being used (any change is to be intimated to the Appropriate Authority under rule 13).
  4. Registration No. allotted.
  5. Period of validity of earlier Certificate of Registration. (For renewed Certificate of Registration only)

From .....To.....  
Signature name and designation of  
the Appropriate Authority  
SEAL]

Date:

**FORM C]**

[Refer rules 6(3), 6(5) and 8(3)]

**REJECTION OF APPLATION FOR GRANT / RENEWAL OF  
REGISTRATION**

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

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

1. Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003.

2. Read as "The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994)"

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

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

Date:

Place:

\*Strike out whichever is not applicable or necessary.]

**<sup>1</sup>[FORM D**

[Refer rule 9 (2)]

MAINTENANCE OF RECORDS BY THE GENETIC COUNSELLING  
CENTRE.

1. Name and address of Genetic Counselling Centre.
2. Registration No.
3. Patient's Name
4. Age
5. Husband's/Father's Name
6. Full address with Tel. No., if any
7. Referred by (Full name and address of Doctor(s) with registration No. (s) (Referral note to be preserved carefully with case papers)
8. Last menstrual period /weeks of pregnancy
9. History of genetic/medical disease in the family (specify) Basis of diagnosis:
  - (a) Clinical
  - (b) Bio-chemical
  - (c) Cytogenetic
  - (d) Other (e.g. radiological, ultrasonography)
10. Indication for pre-natal diagnosis
  - A. Previous child/children with:
    - (i) Chromosomal disorders
    - (ii) Metabolic disorders
    - (iii) Congenital anomaly
    - (iv) Mental retardation
    - (v) Haemoglobinopathy
    - (vi) Sex linked disorders
    - (vii) Single gene disorder
    - (viii) Any other (specify)
  - B. Advanced maternal age (35 years or above)
  - C. Mother/father/sibling having genetic disease (specify)
  - D. Others (specify)
11. Procedure advised<sup>2</sup>
  - (i) Ultrasound

1. Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003.

2. Strike out whichever is not applicable or necessary.

- (ii) Amniocentesis
- (iii) Chorionic villi biopsy
- (iv) Foetoscopy
- (v) Foetal skin or organ biopsy
- (vi) Cordocentesis
- (vii) Any other (specify)
12. Laboratory tests to be carried out
  - (i) Chromosomal studies
  - (ii) Biochemical studies
  - (iii) Molecular studies
  - (iv) Preimplantation genetic diagnosis
13. Result of diagnosis  
If abnormal give details. Normal/ Abnormal
14. Was MTP advised?
15. Name and address of Genetic Clinic\* to which patient is referred.
16. Dates of commencement and completion of genetic counselling.  
Name, Signature and Registration No of the Medical Geneticist/  
Gynaecologist /Paediatrician administering Genetic Counselling.  
Name, Signature and Registration No. of the  
Medical Geneticist/Gynaecologist/Paediatrician  
administering Genetic Counseling.

Place :

Date :]

**<sup>1</sup>[FORM E**

[Refer rule 9(3)]

MAINTENANCE OF RECORDS BY GENETIC LABORATORY

1. Name and address of Genetic Laboratory
2. Registration No.
3. Patient's Name
4. Age
5. Husband's/ Father's name
6. Full address with Tel. No, if any
7. Referred by/sample sent by (full name and address of Genetic Clinic) (Referral note to be preserved carefully with case papers)
8. Type of sample : Maternal blood/Chorionic villus sample/ amniotic fluid/Foetal blood or other foetal tissue (specify)
9. Specify indication for pre-natal diagnosis
  - A. Previous child/children with
    - (i) Chromosomal disorders
    - (ii) Metabolic disorders
    - (iii) Malformations(s)
    - (iv) Mental retardation
    - (v) Hereditary haemolytic anaemia

1. Substituted vide GSR 109(e), dt. 14-2-2003, w.e.f. 14-2-2003

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

Signature: \_\_\_\_\_

Date : \_\_\_\_\_ Name in Capitals, Registration Number with Seal of the Gynaecologist/Radiologist/Registered Medical Practitioner Conducting Diagnostic Procedure

**<sup>1</sup>FOMG**  
[Refer rule 10]  
**CONSENT**

(For invasive techniques)

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

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

I undertake not to terminate the pregnancy if the pre-natal procedure/technique /test conducted show the absence of disease/deformity/ disorder.

I understand that the sex of the foetus will not be disclosed to me.

I understand that breach of this undertaking will make me liable to penalty as prescribed in the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994)<sup>2</sup> and rules framed thereunder.

Date: \_\_\_\_\_ Signature of the pregnant woman

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

Name, Signature and Registration Number of Gynaecologist /Medical Geneticist/ Radiologist /Paeditrician/Director of the Clinic/Centre/Laboratory

Date: \_\_\_\_\_ Name, Address and Registration number of Genetic Clinic/Institution  
SEAL]

1. Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003.  
2. Ead as "The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994)"

(Referral slips to be preserved carefully with Form F)

(b) **Self-Referral** by Gynaecologist/Radiologist/Registered Medical Practitioner conducting the diagnostic procedures: \_\_\_\_\_

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

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

8. Last menstrual period or weeks of pregnancy : \_\_\_\_\_

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

9. Name of the doctor performing the procedure/s : \_\_\_\_\_

10. Indication/for diagnosis procedure : \_\_\_\_\_ (specify with reference to the request made in the referral slip or in a self-referral note)

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

- i. To diagnose intra-uterine and/or ectopic pregnancy and confirm viability.
- ii. Estimation of gestational age (dating).
- iii. Detection of number of fetuses and their chorionicity.
- iv. Suspected pregnancy with IUCD in-situ or suspected pregnancy following contraceptive failure/MTP failure.
- v. Vaginal bleeding/leaking.
- vi. Follow-up of case of abortion.
- vii. Assessment of cervical canal and diameter of internal os.
- viii. Discrepancy between uterine size and period of amenorrhoea.
- ix. Any suspected adnexal or uterine pathology/abnormality.
- x. Detection of chromosomal abnormalities, fetal structural defects and other abnormalities and their follow-up.
- xi. To evaluate fetal presentation and position.
- xii. Assessment of liquor amnii.
- xiii. Preterm labour / preterm premature rupture of membranes.
- xiv. Evaluation of placental position, thickness, grading and abnormalities (placenta praevia, retro placental hemorrhage, abnormal adherence etc.)
- xv. Evaluation of umbilical cord-presentation, insertion, nuchal encirclement, numbers of vessels and presence of true knot.
- xvi. Evaluation of previous Caesarean Section scars.
- xvii. Evaluation of fetal growth parameters, fetal weight and fetal well being.
- xviii. Color flow mapping and duplex Doppler studies.
- xix. Ultrasound guided procedures such as medical termination of pregnancy, external cephalic version etc. and their follow-up.
- xx. Adjunct to diagnostic and therapeutic invasive interventions such as chorionic villus sampling (CVS), amniocenteses, fetal blood sampling, fetal skin, biopsy, amnio-infusion, intrauterine infusion, placement of shunts etc.
- xxi. Observation of intra-partum events.

- xxii. Medical/surgical conditions complicating pregnancy.  
 xxiii. Research/scientific studies in recognized institutions.
11. Procedures carried out (Non-Invasive) (Put a "Tick" on the appropriate procedure)  
 i. Ultrasound  
 (Important Note: Ultrasound is not indicated/advised/performed to determine the sex of fetus except for diagnosis of sex linked diseases such as Duchene Muscular Dystrophy, Hemophilia A & B etc.)  
 ii. Any other (specify) \_\_\_\_\_
12. Date of which declaration of pregnant woman/person was obtained: \_\_\_\_\_  
 13. Date of which procedures carried out : \_\_\_\_\_  
 14. Result on which procedures carried out: \_\_\_\_\_  
 15. The result of pre-natal diagnostic procedures was conveyed to \_\_\_\_\_ on \_\_\_\_\_.  
 16. Any indication for MTP as per the abnormality detected in the diagnostic procedures/tests \_\_\_\_\_

Date : \_\_\_\_\_ **Name, Signature and Registration Number with Seal of the Gynaecologist/Radiologist/Registered Medical Practitioner performing Diagnostic Procedure/s**  
 Place: \_\_\_\_\_

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

17. Name of the doctor/s performing the procedure/s : \_\_\_\_\_  
 18. History of genetic/medical disease in the family (specify): \_\_\_\_\_  
 Basis of diagnosis ("Tick" on appropriate basis of diagnosis):  
 (a) Clinical (b) Bio-chemical  
 (c) Cytogenetic (d) Other (e.g. radiological, ultrasonography etc. specify)  
 19. Indication/s for the diagnosis procedure ("Tick" on appropriate basis of indication/s)  
**A.** Previous child/children with:  
 (i) Chromosomal disorders (ii) Metabolic disorders  
 (iii) Congenital anomaly (iv) Mental Disability  
 (v) Haemoglobinopathy (vi) Sex lined disorders  
 (vii) Single gene disorder (viii) Any other (specify)  
**B.** Advanced maternal age (35 years)  
**C.** Mother/father/sibling has genetic disease (specify)  
**D.** Other (specify) \_\_\_\_\_  
 20. Date on which consent of pregnant woman / person was obtained in Form G prescribed in PC & PNDT Act, 1994 \_\_\_\_\_  
 21. Invasive procedures carried out ("Tick" on appropriate basis of indication/s)  
 (i) Amniocentesis (ii) Chorionic Villi aspiration  
 (iii) Fetal biopsy (iv) Cordocentesis  
 (v) Any other (specify)  
 22. Any complication/s of invasive procedure (specify) : \_\_\_\_\_

23. Additional tests recommended (Please mention if applicable):  
 (i) Chromosomal studies (ii) Biochemical studies  
 (iii) Molecular studies (iv) Pre-implanation gender diagnosis  
 (v) Any other (specify) \_\_\_\_\_  
 24. Result of the procedures/Tests carried out (report in brief of the invasive tests/procedures carried out) \_\_\_\_\_  
 25. Date on which procedures carried out: \_\_\_\_\_  
 26. The result of pre-natal diagnostic procedures was conveyed to \_\_\_\_\_ on \_\_\_\_\_  
 27. Any indication for MTP as per the abnormality detected in the diagnostic procedures/tests: \_\_\_\_\_

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

**Section D: Declaration**  
**DECLARATION OF THE PERSON UNDERGOING PRE-NATAL DIAGNOSTIC TEST/PROCEDURE**

**গৰ্ভপূৰ্বক পৰীক্ষা/পদ্ধতি গ্ৰহণকাৰীৰ ঘোষণা**  
 I, Mrs./Mr. \_\_\_\_\_ declare that by undergoing \_\_\_\_\_ Pre-natal diagnostic test/procedure. I do not want to know the sex of my foetus.  
 মই শ্ৰী/শ্ৰীমতী ..... ঘোষণা কৰো যে গৰ্ভপূৰ্বক পৰীক্ষা/পদ্ধতি গ্ৰহণৰ দ্বাৰা ভ্ৰূণৰ লিঙ্গ জানিবলৈ বিচৰা নাই।  
 Date : \_\_\_\_\_

Signature/Thumb impression of the person undergoing the Pre-natal Diagnostic Test/Procedure  
 তাং- \_\_\_\_\_ পদ্ধতি গ্ৰহণকাৰী মহিলা/ব্যক্তিৰ স্বাক্ষৰ/বুঢ়া আঙুলিৰ টিপচহী বা ছাপ  
**In Case of thumb Impression :**  
 বুঢ়া আঙুলিৰ টিপচহী বা ছাপ দিওঁতাৰ ক্ষেত্ৰতঃ  
 Identified by (Name) \_\_\_\_\_ Age \_\_\_\_\_ Sex \_\_\_\_\_  
 চিনাক্তকাৰীৰ নামঃ \_\_\_\_\_ বয়স \_\_\_\_\_ লিঙ্গ \_\_\_\_\_

Relation (if any): \_\_\_\_\_ Address & Contact No. \_\_\_\_\_  
 সম্বন্ধ (যদি হয়) : \_\_\_\_\_ ঠিকনা ও যোগাযোগৰ ফোন নং \_\_\_\_\_  
 Signature of a person attesting thumb impression: \_\_\_\_\_ Date \_\_\_\_\_  
 স্বাক্ষৰ : (চিনাক্তকাৰীৰ) \_\_\_\_\_ তাং- \_\_\_\_\_

**DECLARATION OF DOCTOR/PERSON CONDUCTING PRE-NATAL DIAGNOSTIC PROCEDURE/TEST**



## 1[FORM H

[Refer rule 9(5)]

### MAINTENANCE OF PERMANENT RECORD OF APPLICATIONS FOR GRANT/ REJECTION OF REGISTRATION UNDER THE PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) ACT, 1994<sup>2</sup>

#### 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

Meeting 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. Decision 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.

\*\*\*\*\*

1. Sl No.
2. File number of Appropriate Authority
3. Date of receipt of application for grant of registration.
4. Name, Address, Phone /Fax etc., of Applicant
5. Name and address(es) of Genetic Counselling Centre\*/Genetic Laboratory\*/Genetic Clinic\*/Ultrasound Clinic\*/Imaging Centre\*.
6. Date of consideration by Advisory Committee and recommendation or Advisory Committee, in summary.
7. Outcome of application (state granted/rejected and date of issue of orders -record date of issue of order in Form B or Form C).
8. Registration number allotted and date of expiry of registration.
9. Renewals (date of renewal and renewed upto).
10. File number in which renewals dealt.
11. Additional information, if any.

Name, Designation and Signature of  
Appropriate Authority

#### Guidance for Appropriate Authority

- (a) Form H is a permanent record to be maintained as a register, in the custody of the Appropriate Authority.
- (b) \*Means strike out whichever is not applicable.
- (c) On renewal, the Registration Number of the Genetic Counselling Centre\*/Genetic Laboratory\*/Genetic Clinic\*/Ultrasound Clinic\*/Imaging Centre\* will not change. A fresh registration Number will be allotted in the event of change of ownership or management
- (d) Registration number shall not be allowed twice.
- (e) Each Genetic Counselling Centre\*/Genetic Laboratory\*/Genetic Clinic\*/Ultrasound Clinic\*/Imaging Centre\* may be allotted a folio consisting of two pages of the Register for recording Form G.
- (f) The space provided for 'additional information' may be used for recording suspension, cancellations, rejection of application for renewal, change of ownership/management, outcome of any legal proceedings, etc.
- (g) Every folio (i.e. pages) of the Register shall be authenticated by signature of the the Appropriate Authority with date, and every subsequent entry shall also be similarly authenticated.]

Note: The Principal Notification was published in the Gazette of India vide No. GSR 1(E), dt. 1-1-1996 and last Notification No. GSR 109(E), dt 14-2-2003.

1. Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003.
2. Read as "The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994)".

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

[GSR 540 (E), dated 26-11-1996]

In exercise of the powers conferred by Section 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, 1996.1

(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;
- (c) "Chairman" means the Chairman of the Advisory Committee appointed under sub-section (5) of section 17;
- (d) "Principal rules" means the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996;2
- (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 meaning, respectively, assigned to them in the Act or in the principal rules.

## 3. Terms and conditions of an 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 State Government, as the case may be, involves moral turpitude; or
- (b) Is an undischarged insolvent; or

1. Now "the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Advisory Committee) Rules, 1996.

2. Now "the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996.

- (c) is not of sound mind and stands so declared by a competent Court; or
- (d) has in the opinion of the Central Government or the State Government as the case may be, such
- (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 (sic) 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 travelling 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 principal 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.

### 4. 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 Chairperson or on his motion.