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

[Act 57 of 1994]

[As amended by Act 14 of 2003, w.e.f. 14-2-2003 Vide SO 175(E), dt 14-2-2003] Along with

 The Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Rule, 1996

[As amended vide GRS 418 (E), dt. 4-6-2012, w.e.f. 5-6-2-2012]

• The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) (Advisory Committees) Rules, 1996

BARE ACT

(English & Assamese)
With Short Comments

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PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION)

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BARE ACT

With Short Comments

ORIGINAL PUBLICATION COMMERCIAL LAW PUBLISHERS (INDIA) PVT. LTD.

INTRODUCTORY

The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act. 1994, is an Act to provide for the prohibition of sex selection, before or after conception, and for regulation of pre-natal diagnostic techniques for the purposes of detecting genetic malformations or sex-linked disorders and for the prevention of their misuse for sex determination leading to female foeticide and for matters connected therewith or incidental thereto. The Act is intended to prohibit pre-natal diagnostic techniques for determination of sex of the foetus leading to female foeticide. Such abuse of techniques is discriminatory against the female sex and affects the dignity and status of women. A legislation was required to regulate the use of such techniques and to provide deterrent punishment to stop such inhuman act. Hence, the Preconception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994.

The Act provides for-

- Prohibition of the misuse of pre-natal diagnostic techniques for determination of sex of foetus leading to female foeticide;
- (ii) Prohibition of advertisement of pre-natal diagnostic technique for detection or determination of sex;
- (iii) Permission and regulation of the use of pre-natal diagnostic techniques for the purpose of detection of specific genetic abnormalities or disorders;
- (iv) Permitting the use of such techniques only under certain conditions by the registered institutions; and
- (v) Punishment for violation of the provisions of the proposed legislation.

This concise edition comprises the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Acct, 1994, as amended by Amendment Act 14 of 2003, w.e.f. 14-2-2003 vide SO 175(E), dt. 14-2-2003, with short comments along with the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996 also have been thoroughly amended vide GSR 418(E), dt. 4-6-2012, w.e.f. 5-6-2012 and the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) (Advisory Committees) Rules, 1996, is intended for the readers to have a first hand information of the subject.

A creative feedback from the learned readers, bringing to our notice any mistake, error or omission or discrepancy that might have crept in this book in spite of our sincere efforts to avoid those, is most welcome, for it will help us to improve the overall quality, style and presentation of the book in the forthcoming editions.

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- (bb) "embryo" means developing human organism after fertilisation till the end of eight weeks (fifty six days);
- (bc) "foetus" means a human organism during the period of its development beginning on the fifty-seventh day following fertilisation or creation (excluding any time in which its development has been suspended) and ending at the birth";
- (ii) in clause (d), the following Explanation shall be added, namely:"Explanation: For the purpose of this clause, "Genetic Clinic' includes a vehicle, where ultrasound machine or imaging machine or scanner or other equipment Capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception is used;"
- (iii) in clause (e), the following Explanation shall be added, namely:"Explanation; For the purposes of this clause, "Genetic Laboratory"
 includes a place where ultrasound machine or imaging machine or
 scanner or other equipment capable of determining sex of the foetus
 or a portable equipment which has the potential for detection of sex
 during pregnancy or selection of sex before conception, is used,;
- (iv) for clause (g), the following clause shall be substituted, namely:-(g)"medical geneticist" includes a person who possesses a degree or diploma in genetic science in the fields of sex selection and prenatal diagnostic techniques or has experience of not less than two years in any of these fields after obtaining—
 - (i) any one of the medical qualifications recognized under the Indian Medical Council Act, 1956 (102 of 1956); or
 - (ii) a post-graduate degree in biological science;';
- (v) for clause (i), the following clause shall be substituted, namely:-'(i)" pre-natal diagnostic procedures" means all gynaecological or obstetrical or medical procedure such as ultrasonography, foetoscopy taking or removing samples of amniotic fluid, chorionic villi, embryo, blood or any other tissue or fluid of a man, or of a woman before or after conception, for being sent to a Genetic Laboratory or Genetic Clinic for conducting any type of analysis or pre-natal diagnostic tests for selection of sex before or after conception,';
- (vi) for clause (k), the following clause shall be substituted, namely:-'(k) "pre-natal diagnostic test" means ultrasonography or any test or analysis of amniotic fluid, chorionic villi, blood or any tissue or fluid of a pregnant women or conceptus conducted to detect genetic or metabolic disorders or chromosomal abnormalities or congenital anomalies or haemoglobinpathies or sex-linked diseases;';
- (vii) After clause (n), the following clauses shall be inserted, namely:'(o)"Sex selection" includes any procedure, technique, test or administration
 or prescription or provision of anything for the purpose of ensuring or
 increasing the probability that an embryo will be of a particular sex;
 (p) "sonologist or imaging specialist" means a person who possesses any
 one of the medical qualifications recognized under the Indian Medical
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THE PRE-NATAL DIOAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) AMENDMENT ACT, 2002

(14 of 2003, dt. 17-1-2003)

An Act further to amend the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994.

Be it enacted by Parliament in the Fifty-third year of the Republic of India as follows: —

1. Short title and commencement

- (1) This Act may be called the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002
- (2) It shall come into force on such date¹ as the Central Government may, by notification in the Official Gazette, appoint.

2. Substitution of long title

In the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994) (hereinafter referred to as the principal Act.) for the long title, the following long title shall be substituted, namely: —

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

3. Amendment of section 1

In section 1 of the principal Act, in sub-section (1) for the words and brackets "The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse)", the words and brackets "the Pre-conception and pre-natal Diagnostic Techniques (Prohibition of Sex Selection)" shall be substituted.

4. Amendment of section 2

In section 2 of the principal Act,-

(i) After clause (b), the following clauses shall be inserted, namely:-'(ba) "conceptus" means any product of conception at any stage of development from fertisation until birth including extra embryonic membranes as well as the embryo or foetus;

¹ W.e.f. 14-2-2003 vide SO 175(E), dt. 14-2-2003

- (ii) eminent women activities from non-governmental organisations or otherwise;
- (iii) eminent gynaecologists and obstetricians or experts of striroga or prasuti-tantra;
- (iv) eminent paediatricians or medical geneticists;
- (v) eminent radiologists or sinologists;
- (g) an officer not below the rank of Joint Director in charge of Family Welfare, who shall be the Member Secretary, ex officio.
 - (3) The State Board shall meet at least once in four months.
 - (4) The term of office of a member, other than an ex officio member, shall be three years

(5) If a vacancy occurs in the office of any member other than an ex

officio member, it shall be filled by making fresh appointment.

- (6) If a member of the Legislative Assembly or member of the Legislative Council who is a member of the State Board, becomes Minister or Speaker or Deputy Speaker of the Legislative Assembly or Chairperson or Deputy Chairperson of the Legislative Council, she shall cease to be a member of the State Board.
- (7) One –third of the total number of members of the State Board shall constitute the quorum.
- (8) The State Board may co-opt a member as and when required, provided that the number of co-opted members does not exceed one-third of the total strength of the State Board.
- (9) The co-opted members shall have the same powers and functions as other members, except the right to vote and shall abide by the rules and regulations.
- (10) In respect of matters not specified in this section, The State Board shall follow procedures and conditions as are applicable to the Board."

15. Amendment of section 17

In section 17 of the principal Act,-

- (i) In sub-section (3), for clause (a), the following clause shall be substituted, namely:-
- "(a) when appointed for the whole of the State or the Union territory, consisting of the following three members-
- (i) An officer of or above the rank of the Joint Director of Health and Family Welfare Chairperson;
- (ii) An eminent woman representing women's organization; and
- (iii) An officer of law Department of the State or the Union territory concerned:
 - PROVIDED that is shall be the duty of the State or the Union territory concerned to constitute multi-member State or Union territory level Appropriate Authority within three months of the coming into force of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act. 2002:
 - PROVIDED FURTHER that any vacancy occurring therein shall be filled within three months of the occurrence.",
- (ii) In sub-section (4), after clause (d), the following clauses shall be inserted namely:-

- (q) "State Board" means a State Supervisory Board or a Union territory Supervisory Board constitution under section 16A;
- (r) "State Government" in relation to Union territory with Legislature means the Administrator of that Union territory appointed by the President under article 239 of Constitution'.

5. Amendment of section 3

In section 3 of the principal Act, for clause (2), the following clause shall be substituted namely-

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

6. Insertion of new sections 3A and 3B

After section 3 of the principal Act, the following sections shall be inserted, namely:-

"3A. Prohibition of sex selection--No person, including a specialist or a team of specialist in the field or infertility shall conduct or cause to be conducted or aid in conducting by himself or by any other person, sex selection on a woman or a man or on both or on any tissue, embryo, conceptus, fluid or gametes derived from either or both of them.

3B. Prohibition on sale of ultrasound machine, etc., to persons, laboratories, clinics, etc. not registered under the Act-- No person shall sell any ultrasound machine or imaging machine or scanner or any other equipment capable of detecting sex of the foetus to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic or any other person not registered under the Act."

7. Amendment of section 4

In section 4 of the principal Act, for clauses (3) and (4), the following clauses shall be substituted namely:-

- "(3) no pre-natal diagnostic techniques shall be used or conducted unless the person qualified to do so is satisfied for reasons to be recorded in writing that any of the following conditions are fulfilled, namely:-
- (i) age of the pregnant woman is above thirty –five years;
- (ii) the pregnant woman has undergone two or more spontaneous abortions or foetal loss;
- (iii) the pregnant woman had been exposed to potentially teratogentic agents such as drugs, radiation, infection or chemicals;
- (iv) the pregnant woman or her spouse has a family history of mental retardation or physical deformities such as, spasticity or any other genetic disease;
- (v) any other condition as may be specified by the Board:
- (vii) PROVIDED that the person conducting ultrasonography on a pregnant woman shall keep complete record thereof in the clinic in such manner, as may be prescribed, and any deficiency or inaccuracy found therein shall amount to contravention of the provisions of section 5 or section 6 unless contrary is proved by the person conducting such ultrasonography;

- (4) no person including a relative or husband of the pregnant woman shall seek or encourage the conduct of any pre-natal diagnostic techniques on her except for the purposes specified in clause (2);
- (5) no person including a relative or husband of a woman shall seek or encourage the conduct of any sex-selection technique on her or him or both."

8. Amendment of section 5

In section 5 of the principal Act, for sub-section (2), the following sub-section shall be substituted, namely:-

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

9. Amendment of section 6

In section 6 of the principal Act, after clause (b), the following clause shall be inserted namely:-

"(c) no person shall, by whatever means, cause or allow to be caused selection of sex before or after conception."

10. Amendment of section 7

In section 7 of the principal Act.-

(i) in sub-section (2), for clause (c), the following clause shall be substituted, namely:-

- "(c) three members to be appointed by the Central Government to represent the Ministries of Central Government in charge of Women and Child Development, Department of Legal affairs or Legislative Department in the Ministry of Law and Justice, and Indian System of Medicine and Homoeopathy, ex officio.';
- (ii) in clause (e), for sub-clause (ii), the following sub-clause shall be substituted, namely:-
- "(ii) eminent gynaecologist and obstetrician or expert of Stri-roga or prasutitantra.".

11. Amendment of section 14

In section 14 of the principal Act. For clause (f), the following clause shall be substituted, namely:-

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

12. Amendment of section 15

In section 15 of the principal Act, the following proviso shall be inserted, namely:- "PROVIDED that no member other than an ex officio member shall be appointed for more than two consecutive terms."

13. Substitution of new section for section 16

For section 16 of the principal Act, the following section shall be substituted, namely:-

- "16. Functions of the Board The Board shall have the following functions, namely:-
 - (i) to advice the Central Government on policy matters relating to use of pre-natal diagnostic, techniques, sex selection techniques and against their misuse;

- (ii) to review and monitor implementation of the Act and rules made there under and recommend to the Central Government changes in the said Act and rules;
- (iii) to review and monitor implementation of the Act and rules made there under and recommend to the Central Government changes in the said Act and rules;
- (iv) to create public awareness against the practice of preconception sex selection and pre-natal determination of sex foetus leading to female foeticide;
- (v) to lay down code of conduct to be observed by persons working at Genetic Counseling Centres, Genetic Laboratories and Genetic Clinics;
- (vi) to oversee the performance of various bodies constituted under the Act and take appropriate steps to ensure its proper and effective implementation;

(vii) any other functions may be prescribed under the Act."

14. Insertion of new section 16A

After section 16 of the principal Act, the following section shall be inserted, namely:-

"16A. Constitution of State Supervisory Board and Union territory Supervisory Board- (1) Each State and Union territory having Legislative shall constitute a Board to ba known as the State Supervisory Board or the Union territory Supervisory Board, as the case may be, which shall have the following functions:-

- (i) to creat public awareness against the practice of preconception sex selection and pre-natal determination of the sex of the foetus leading to female foeticide in the State;
- (ii) to review the activities of the Appropriate Authorities functioning in the State and recommend appropriate action against them.
- (iii) to monitor the implement of provisions of the Act and the rules and make suitable recommendations relating thereto, to the Board;
- (iv) to send such consolidated reports as may be prescribed in respect of the various activities undertaken in the State under the Act to the Board and the Central Government; and
- (v) any other functions as may be prescribed under the Act.
- (2) The State Board shall consist of,-
 - (a) the Minister in charge of Health and Family Welfare in the State, who shall be the Chairperson, ex officio;
 - (b) Secretary in charge of the Department of Health and Family Welfare who shall be the Vice-Chairperson, ex officio;
 - (c) Secretaries or Commissioner in charge of Departments or Women and Child Development, Social Welfare, Law and Indian System of Medicines and Homoeopathy, ex officio, or their representatives;
 - (d) Director of Health and Family Welfare or Indian System of Medicines and Homoeopathy of the State Government, ex officio;
 - (e) three women members of Legislative Assembly or Legislative Council;
 - (f) ten members to be appointed by the State Government out of which two each shall be from the following categories,-
 - (i) eminent social scientists and legal experts;

THE PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES (PROBITION OF SEX SELECTION) AMENDMENT RULES, 2012

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

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

- 1. (1) These rules may be called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Amendment Rules, 2012.
- (2) They shall come into force on the date of their publication in the Official Gazette.
- 2. In the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996 (hereinafter referred to as the said rules), after rule 3, the following shall be inserted, before rule 3A, namely:-
- "(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."
- 3. In the said rules, in rule 5 in sub-rule (1), the following sub-rule,-
- (a) In item (a) for the letters and figure "Rs. 3,000.00", the words "rupees twenty-five thousand" shall be substituted.
- (b) In item (b) for the letters and figure "Rs. 4,000.00", the words "rupees thirty-five thousand" shall be substituted.
- 4. In the said rules, in rule 13, for the words "within a period of thirty days of such change", the words "atleast 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" shall be substituted.

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- "(e) to take appropriate legal action against the use of any sex selection technique by any person at any place, suomotu or brought to its notice and also to initiate independent investigations in such matter;
- (f) to create public awareness against the practice of sex selection or pre-natal determination of sex;
- (g) to supervise the implementation of the provisions of the Act and rules; (h) to recommend to the Board an State Boards modifications required in the rules in accordance with changes in technology or social conditions;
- (i) to take action on the recommendations of the Advisory Committee made after investigation of complaint for suspension or cancellation of registration."
- (iii) for sub-section (7), the following sub-section shall be substituted, namely: "(7) No person who has been associated with the use or promotion of pre-natal diagnostic techniques for determination of sex or sex selection shall be appointed as a member for the Advisory Committee".

16. Insertion of new section 17A

After section 17 of the principal Act, the following section shall be instead, namely:-

"17A Power of Appropriate Authorities- The Appropriate Authority shall have the powers in respect of the following matters, namely:-

- (a) summoning of any person who is in possession of any information relating to violation of the provisions of this Act the rules made there under;
- (b) production of any document or material object relating to clause(a);
- (c) issuing search warrant for any place suspected to be indulging in sex selection techniques or pre-natal sex determination; and
- (d) any other matter which may be prescribed."

17. Amendment of section 18

In section 18 of the principal Act, for sub-section (1), the following sub-section shall be substituted, namely:-

"(1) No person shall open any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, including clinic, laboratory or centre having ultrasound or imaging machine or scanner or any other technology capable of undertaking determination of sex of foetus and sex selection or render services to any of them, after the commencement of the Pre-natal Diagnostic Techquines (Regulation and Prevention of Misuse) Amendment Act. 2002 unless such Centre, Laboratory or Clinic is duly registered under the Act."

18. Substitution of new section for section 22

For section 22 of the principal Act, the following section shall be substituted, namely:-

*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 the foetus or sex selection shall issue, published, distributed, communicated or cause to be issued, published, distributed or communicated any advertisement, in any form, including internet, regarding facilities of pre-natal determination of sex of 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 provisions of sub-section (1) or sub-section (2) Shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend thousand rupees.

Explanation: For the purpose of this section, "advertisement" includes any notice, circular, lavel, wrapper or any other document including advertisement through internet or any other media in electronic or print form an also includes any visible representation made by means of any hoarding, wall-painting, signal,, light, sound, smoke or gas."

19. Amendment of section 23

In section 23 of the principal Act, for sub-sections (2) and (3), the following sub-section shall be substituted, namely:-

- (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 of the charges are framed by the court and till the case is disposed of and on conviction for removal of his name from the register of the Council for a period of five years for the first offence and permanently for the subsequent offence.
- (3) Any person who seeks the aid of any Genetic Councelling 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 purposes other than those specified in sub-section (2) of section 4, he shall, be punishable with imprisonment for a term which may extend to three years and with fine which may extend to fifty thousand rupees for the first offence and for any subsequent offence with imprisonment which may extend to five years and which fine which may extend to one lakh rupees.
- (4) For the removal of doubts, it hereby provided that the provisions of sub-section (3) shall not apply to the woman who compelled to undergo such diagnostic technique or such selection."

20. Substitution of new section for section 24

For section 24 of the principal Act, the following section shall be substituted, namely: "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 woman 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 abetment of offence under sub-section (3) of section 23 and shall be punishable for the offence specified under that section."

21. Amendment of section 28

In section 28 of the principal Act, in sub-section (1) in clause (b) for the words "thirty days", the words "fifteen days" shall be substituted.

22. Amendment of section 30

In section 30 of the principal Act, for sub-section (1), the following sub-section shall be substituted, namely:-

"(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 authorised 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."

23. Insertion of new section 31A

After section 31 of the principal Act, the following section shall be inserted, namely:-

*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 provision 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 Prenatal Diagnostic Technique (Regulation and Prevention of Misuse) Amendment Act, 2002.

(2) Every order made under this section shall be laid, as soon as may be after it is made before each House of Parliament."

24. Amendment of section 32

In section 32 of the principal Act, in sub-section (23)-

- (i) for clause (i), the following clauses shall be substituted, namely:-
- "(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,;
- (ii) After clause(iv), the following clauses shall be inserted, namely:-
- "(iva) code of conduct to be observed by persons working at Genetic Counselling Centres, Genetic Laboratories and Genetics Clinics 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 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;".

Embryo

Embryo is the entity which develops in a woman's womb unit it is born as baby (if not aborted, etc) Now especially this entity prior to the time at which all the organs are developed, at about the eighth week after conception (cf, foetus); in Med. Sometimes also distinguished from the conceptus or preembryo.- The New Shorter Oxford English Dictionary.

Émbryo is an unborn on unhatched offspring in the process of development, especially an unborn human in the first eight weeks from

conception - Concise Oxford Dictionary.

Foetus

Foetus is a baby in the womb; an unborn child; an infant in ventra sa mere, An unborn viviparaous animal in the womb, an unhatched oviparous animal in the egg; esp an unborn human more than eight weeks after conception.- The New Shorter Oxford English Dictionary.

Genetic counseling

Genetic code is the basis on which genetic information is stored as sequences of nucleotides in chromosomal DNA or RNA, different groups of three consecutive nucleotides corresponding to different amino acids. Genetic councelling relates to prospective parents concerning the chances of genetic disorders in a future child. Genetic drift is the variation in the relative frequency of different genotypes in a small population owing to the chance disappearance of particular genes as individuals die or do not reproduce.

Genetic engineering is the manipulation of genetic material in order to

alter genes and hence the characteristics of the organism concerned.

Genetic fingerprint is a set of genetic characteristics derived from the tissues or secretions of an individual and used to identify him or her. Genetic profile is a description listing the significant genetic characteristics of an individual and used for identification, the prediction of inherited disorders, etc. *Gunaecologist*

Gynaecology is the branch of medicine that deals with the physiology and diseases of women and girls, especially of their reproductive organs.

The New Shorter Oxford English Dictionary.

Gynaecology is the branch of physiology and medicine concerned with the functions and diseases specific to women and girls; specially those affecting the reproductive system.- Concise Oxford Dictionary.

A Gynaecologist is a doctor who studies and treats the medical conditions

and diseases of women.

Obstetrics is the branch of medicine that deals with childbirth and the care and treatment of the mother before and after birth, the practice of midwifery.

Paediatrician

Paediatric means of or pertaining to Paediatrics or the diseases of children, Paediatrics is the branch of medical science that deals with childhood and the diseases of children. Paediatrician is a doctor who specialises in paediatrics.

Pre-natal diagnostic procedures

The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 is an Act provide for the regulation of the use of pre-natal diagnostic techniques for the purpose of detecting genetic or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex-linked disorders and for the prevention of the misuse of such techniques for the purpose of pre-natal sex determination leading to female foeticide;

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

(Act No. 57 of 1994, dt. 20-9-1994)

(As amended by Amendment Act, 2002, w.e.f. 14-2-2003)

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

BE it enacted by Parliament in the Forty-fifth year of the Republic of India as follows:-

CHAPTER I

PRELIMINARY

1. Short title, extent and commencement

This Act may be called ²[the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection)] Act, 1994.

- (2) It shall extend to the whole of India except the State of Jammu and Kashmir.
- (3) It shall come into force on such date³ as the Central Government may, by notification in the Official Gazette, appoint.

2. Definitions

In this Act, unless the context otherwise requires,-

- (a) "Appropriate Authority" means the Appropriate Authority appointed under section 17;
- (b) "Board means the Central Supervisory Board constituted under section 7;
- ⁴[(ba) "conceptus" means any product of conception at any stage of development from fertilisation until birth including extra embryonic membranes as well as the embryo or foetus;

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

Substituted, ibid for "the Pre-natal Diagnostic Techniques (Regulation and Prevention of misues)".

^{3.} Became enforceable w.e.f. 1-1-1996 vide GSR 706, dt. 20-12-1995.

^{4.} Inserted vide Act 14 of 2003, w.e.f. 14-2-2003 vide SO 175 (E), dt 14-2-2003.

SECTION 2

- (bb) "embryo" means a developing human organism after fertilisation till the end of eight weeks (fifty-six days);
- (bc) "foetus" means a human organism during the period of its development beginning on the fifty-seventh day following fertilisation or creation (excluding any time in which its development has been suspended) and ending at the birth;]
- (c) "Genetic Counseling Centre" means an institute, hospital, nursing home or any place, by whatever name called, which provides for genetic counselling to patients;
- (d) "Genetic Clinic" means a clinic, institute, hospital, nursing home or any place, by whatever name called, which is used for conducting prenatal diagnostic procedures; ¹[Explanation: For the purpose of this clause, "Genetic Clinic' includes a vehicle, where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex

during pregnancy or selection of sex before conception, is used;

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

 ¹[Explanation: For the purposes of this clause, "Genetic Laboratory" includes a place where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used;]
- (f) "gynaecologist" means a person who possesses a post -graduate qualification in gyanaecology and obstetrics;
- ²[(g) "medical geneticist" includes a person who possesses a degree or diploma in genetic science in the fields of sex selection and prenatal diagnostic techniques or has experience of not less than two years in any of these fields after obtaining-
- (i) any one of the medical qualifications recognised under the Indian Medical Council Act, 1956 (102 of 1956); or
- (ii) "pediatrician" means a person who possesses a post-graduate qualification in paediatrics;
- ²[(i) "pre-natal diagnostic procedures" means all gynaecological or obstetrical or medical procedures such as ultrasonography, foetoscopy, taking or removing samples of amniotic fluid, chorinic villi, embryo, blood or any other tissue or fluid of a man, or of a woman before or after conception, for being sent to a Genetic Laboratory or Genetic Clinic for conducting any type of analysis or pre-natal diagnostic tests for selection of sex before or after conception;]

(j) "pre-natal diagnostic techniques" includes all pre-natal diagnostic procedures and pre-natal diagnostic tests;

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

(l) "prescribed" means prescribed by rules made under this Act;

(m) "registered medical practitioner" means a medical practitioner who possesses any recognized medical qualification as defined in clauses (h) of section 2 of the Indian Medical Council Act, 1956 (102 of 1956), and whose name has been entered in a State Medical Register;

(n) "regulations" means regulations framed by the Board under this Act;

²[(o) "sex selections" includes any procedure, technique, test or administration or prescription or provision of anything for the purpose of ensuring or increasing the probability that an embryo will be of a particular sex;

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

(q) "State Board" means a State Supervisory Board or a Union territory

Supervisory Board constituted under section 16A;

(r) "State Government" in relation to Union territory with Legislature means the Administrator of that Union territory appointment by the President under article 239 of Constitution.]

COMMENTS

Appropriate Authority

Under sub-section (1) of section 17, the Central Government shall appoint one or more appropriate authorities for each of the Union Territories for the purpose of this Act, and under sub-section (2), the State Government shall appoint one or more such authorities for the whole or part of the State for the purposes of the Act having regard to the intensity of the problem of pre-natal sex termination leading to female foeticide. **Board**

Section 7 provides for the constitution of Central Supervisory Board to exercise the powers and perform the functions conferred under the Act. *Conceptus*

Conceptus means conception,, embryo, the product of conception in

the womb, especially in the early stages of pregnancy.

Conception is the beginning of pregnancy. As to human beings, the fecundation of the female ovum by the male spermatozoan resulting in human life capable of survival and maturation under normal conditions-Black's Law Dictionary.

^{1.} Inserted vide Act, 14 2003, w.e.f. 14-2-2-2013 vide SO 175, dt. 14-2-2003,

^{2.} Substituted, ibid.

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

^{2.} Inserted, ibid.

- (iv) Sex-linked genetic diseases;
- (v) Congenital anomalies;
- (vi) Any other abnormalities or diseases as may be specified by the Central Supervisory Board1;
- ²[(3) no pre-natal diagnostic techniques shall be used or conducted unless the person qualified to do so is satisfied for reasons to be recorded in writing that any of the following conditions are fulfilled, namely:

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

- (ii) the pregnant woman has undergone two or more spontaneous abortions or foetal loss;
- (iii) the pregnant woman had been exposed to potentially teratogenic agants such as drugs, radiation, infection or chemicals;
- (iv) the pregnant woman or her spouse has a family history of mental retardation or physical deformities such as , spasticity or any other genetic disease;
- (v) any other condition as may be specified by the Board;
- PROVIDED that the person conducting ultrasonography on a pregnant woman shall keep complete record thereof in the clinic in such manner, as may be prescribed, and any deficiency or inaccuracy found therein shall amount to contravention of the provisions of section 5 or section 6 unless contrary is proved by the person conducting such ultrasonography;
- (4) no person including a relative or husband of the pregnant woman shall seek or encourage the conduct of any pre-natal diagnostic techniques on her except for the purposes specified in clause(2);
- (5) no person including a relative or husband of a woman shall seek or encourage the conduct of any sex-selection technique on her or him both.]

5. Written consent of pregnant woman and prohibition of communicating the sex of foetus

- (1) No person referred to in clause (2) of section 3 shall conduct the pre-natal diagnostic procedures unless-
- (a) he has explained all known side and after effects of such procedures to the pregnant woman concerned;
- (b) he has obtained in the prescribed form her written consent to undergo such procedures in the language which she understands; and
- (c) a copy of her written consent obtained under clause (b) is given to the pregnant woman.
- ²[(2) No person including the person conducting pre-natal diagnostic procedures shall communicate to the pregnant woman concerned or her relatives or any other person the sex of the foetus by words, signs, or in any other manner..]
- 6. Determination of sex prohibited

On and form the commencement of this Act.-

and for matters connected therewith or incidental thereto. Under section 2 (i) of that Act" pre—natal diagnostic procedure" means all gynaecological or obstetrical or medical procedures such as ultrasonography, foetoscopy, taking or removing samples of amniotic fluid, chorionic villi, blood or any tissue of a pregnant woman for being sent to Genetic Laboratory or Genetic Clinic for conducting pre-natal diagnostics tests. *Prescribed*

Section 32 of the Act empowers the Central Government to make rules for carrying out the provisions of the Act, in particular such rules may provide for the purposes enumerated under clauses (i) to (xiv) of sub-section (2) of section 32. *Registered Medical Practitioner*

Recognised medical qualification means any of the medical qualifications included in the Schedules to the Indian Medical Council Act, 1956.

Regulations

SECTION 2

Under Section 33 of the Act, the Central Supervisory Board may, with the previous sanction of the Central Government, by notification in the Official Gazette make regulations not inconsistent with the provisions of the Act and Rules made there under to provide for-

(a) the time and place of the meetings of the Board and the procedure to be followed for the transaction of business at such meetings and the number of members which shall form the quorum under sub-section (1) of section 9;

(b) The manner in which a person may be temporarily associated with the Board under sub-section (1) of section 11.

(c) The method of appointment, the conditions of service and the scales of pay and allowance 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.

Every rule and every regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session of the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both House agree that the rule of 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. Sonologist or imaging specialist

Sonograph is an instrument which analyses sound into its component frequencies and produces a graphical record of the results.

State Board

Section 16A of the Act provides for the constitution of State Supervisory Board and Union Territory Supervisory Board. Accordingly, each State and Union territory having Legislature shall constitute a Board to be known as the State Supervisory Board the Union territory Supervisory Board, as the case may be, which shall have the following functions:-

(i) to create public awareness against the practice of pre-conception of sex selection and pre-natal determination of sex of foetus leading to female foeticide in the State;

(ii) to review the activities of the Appropriate Authorities functioning in the State and recommend appropriate action against them;

(iii) to monitor the implementation of provisions of the Act and the rules and make suitable recommendations relating thereto, to the Board;(iv) to send such consolidated reports as may be prescribed in respect

(iv) to send such consolidated reports as may be prescribed in respect of the various activities undertaken in the State under the Act to the Board and the Central Government; and

^{1.} In exercise of the powers conferred by section 4(2) (vi), the Central Supervisory Board vide SO 189(E), dt. 12-2-2004, has specified as: "any other indication of possible genetic disease/ anomaly in the foetus such as sporadic genetic disease in the couple, a positive screening test for genetic disease/congenital anomaly in pregnancy etc."

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

SECTION 4

- (v) any other functions as may be prescribed under the Act.
- The State Board shall consist of,
 - (a) the Minister in charge of Health an Family Welfare in the State, who shall be the Chairperson, ex officio:

Secretary in charge of the Department of Health and Family Welfare who shall be the Vice - Chairperson, ex offcio;

- Secretaries or Commissioners in charge of Departments of Women and Child Development, Social Welfare, Law and Indian System of Medicines and Homoeopathy, ex officio, or their representatives;
- (d) Director of Health and Family Welfare or Indian System of Medicines and Homoeopathy of the State Government, ex officio;
- three women members of Legislative Assembly or Legislative Council; ten members to be appointed by the State Government out of which two each shall be from the following categories;

(i)eminent women scientists and legal experts;

- (ii) eminent women activists from non-governmental organizations or otherwise:
- (iii) eminent gynaecolosists and obstetricians or experts of stri-roga or prasuti-tantra;
- (iv) eminent peadiatricians or medical geneticists;

(v) eminent radiologists or sonologists;

- (g) an officer not below the rank of Joint Director in charge of Family Welfare, who shall be the Member Secretary, ex officio.
- The State Board shall meet at least once in four months.
- The term of office of a member, other than an ex officio member, shall be three years.

If a vacancy occurs in the office of any member other than an ex officio

- member, it shall be filled by making fresh appointment. If a member of the Legislative Assembly of member of the Legislative Council who is a member of the State Board, becomes Minister or Speaker or Deputy Speaker of the Legislative Assembly or Chairperson or Deputy Chairperson of the Legislative Council, he shall cease to be a member of the State Board.
- One-third of the total number of members of the State Board shall constitute the auorum.
- The State Board may co-opt a member as and when required, provided that the number of co-opted members does not exceed one-third of the total strength of the State Board.
- The co-opted members shall have the same powers and functions as other members, except the right to vote and shall abide by the rules and regulations.
- In respect of matters not specified in this section, the State Board shall follow procedures and conditions as are applicable to the Board.

State Government

Article 239 of the constitution provides for the administration of Union Territories. It says:

- Save as otherwise provided by Parliament by Law, every Union Territory shall be administered by the President acting, to such extent as he thinks fit, through an administrator to be appointed by him with such designation as he may specify.
- Notwithstanding anything contained in part VI, the President may appoint the Governor of a State as the administrator of an adjoining Union Territory, and where a Governor is so appointed, he shall exercise his functions as such admistrator independently of his council of Ministers.

CHAPTER II

REGULALTION OF GENETIC COUNSELLING CENTRES, GENETIC LABORATORIES AND GENETIC CLINIC

3. Regulation of Genetic Counselling Centres, Genetic Laboratories and **Genetic Clinics**

On and from the commencement of this Act-

- (1) no Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic unless registered under this Act, shall conduct or associate with, or help in, conducting activities relating to pre-natal diagnostic techniques;
- ¹[(2) no Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic shall employ or cause to be employed or take services of any person, whether on honorary basis or on payment who does not possess the qualifications as may be prescribed;
- no medical geneticist, gynaecologist paediatrician registered medical practitioner or any other person shall conduct or cause to be conducted or aid in conducting by himself or through any other person, any pre-natal diagnostic techniques at a place other than a place registered under this Act.

²[3A. Prohibition of sex-selection

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

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

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

CHAPTER III

REGULATION OF PRE-NATAL DIAGNOSTIC TECHNIQUES

4. Regulation of pre-natal diagnostics techniques

On and from the commencement of this Act,-

- (1) no place including a registered Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic shall be used or caused to be used by any person for conducting pre-natal diagnostic techniques except for the purposes specified in clause (2) and after satisfying any of the conditions specified in clause (3);
- no pre-natal diagnostic techniques shall be conducted except for the purposes of detection of any of the following abnormalities, namely:-
- chromosomal abnormalities;
- (ii) genetic metabolic diseases;
- (iii) haemoglobinpathies;

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

Inserted, ibid.

15. Eligibility of member for re-appointment

Subject to the other terms and conditions of service as may be prescribed, any person ceasing to be a member shall be eligible for re-appointment as such member

¹[PROVIDED that no member other than an ex officio member shall be appointed for more than two consecutive terms.]

²[16. Functions of the Board

The Board shall have the following functions, namely:-

- to advise the Central Government on policy matters relating to use of pre-natal diagnostic techniques, sex selection techniques and against their misuse;
- (ii) to review and monitor implementation of the Act and rules made there under and recommend to the Central Government changes in the said Act and rules;
- (iii) to create public awareness against the practice of pre-conception sex selection and pre-natal determination of sex of foetus leading to female foeticide;
- (iv) to lay down code of conduct to be observed by the persons working at Genetic counseling Centres, Genetic Laboratories and Genetic Clinics;
- (v) to oversee the performance of various bodies constituted under the Act and taken appropriate steps to ensure its proper and effective implementations;
- (vi) any other functions as may be prescribed under the Act.]

¹[16A. Constitution of State Supervisory Board and Union territory Supervisory Board

- (1) Each State and Union territory having Legislature shall constitute a Board to be known as the State Supervisory Board or the Union territory Supervisory Board, as the case may be, which shall have the following functions:-
 - to create public awareness against the practice of pre-conception sex selection and pre-natal determination of sex of foetus leading to female foeticide in the State;
 - (ii) to review the activities of the Appropriate Authorities functioning in the State and recommend appropriate action against them;
 - (iii) to monitor the implementation of provisions of the Act and the rules and make suitable recommendations relating thereto, to the Board;
 - (iv) to send such consolidated reports as may be prescribed in respect of the various activities undertaken in the State under the Act to the Board and the Central Government; and
 - (v) any other functions as may be prescribed under the Act.
 - (2) The State Board shall consist of,-
 - (a) The Minister in charge of Health and Family Welfare in the State, who shall be the Chairperson, ex, officio;
 - (b) Secretary in-charge of the Department of Health and Family Welfare who shall be the Vice Chairperson, ex officio;

(a) no Genetic Counseling Centre or Laboratory or Genetic Clinic shall conduct or cause to be conducted in its Centre, Laboratory or Clinic, pre-natal diagnostic techniques including ultrasonography, for the purpose of determining the sex of a foetus;

(b) no person shall conduct or cause to be conducted any pre-natal diagnostic techniques including ultrasonography for the purpose

of determining the sex of foetus.

¹[(c) no person shall, by whatever means, cause or allow to be caused selection of sex before or after conception.]

CHAPTER IVCENTRAL SUPERVISORY BOARD

7. Constitution of Central Supervisory Board

- (1) The Central Government shall constitute as Board to be known as the Central Supervisory Board to exercise the powers and perform the functions conferred on the Board under this act.
 - (2) The Board shall consist of -
 - (a) the Minister in charge of the Ministry or Department of Family Welfare, who shall be the Chairman, ex officio;
 - (b) the Secretary to the Government of India in charge of the Department of Family Welfare, who shall be the Vice-Chairman, ex-officio;
 - ²[(c) three members to be appointed by the Central Government to represent the Ministries of Central Government in chargeof Women and Child Development, Department of Legal Affairs or Legislative Department in the Ministry of Law and Justice, and Indian System of Medicine and Homoeopathy, ex officio;]
 - (d) the Director General of Health Services of the Central Government, ex-officio;
 - (e) ten members to be appointed by the Central Government, two each from amongst—
 - (i) eminent medical geneticists;
 - ²[(ii) eminent gynaecologist and obstetrician or expert of stri-roga or prasuti-tantra;]
 - (iii) Eminent paediatricians;
 - (iv) Eminent social scientists; and
 - (v) Representatives of women welfare organizations;
 - (f) three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States;
 - (g) four members to be appointed by the Central Government by rotation to represent the States and the Union territories, two in the alphabetical order and two in the reverse alphabetical order;

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

^{2.} Substituted, ibid.

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

^{2.} Substituted, ibid.

PROVIDED that no appointment under this clause shall be made except on the recommendation of the State Government or, as the case may be, the Union territory;

An officer, not below the rank of a Joint Secretary or equivalent of the Central Government, in charge of Family Welfare, who shall be the Member-Secretary, ex officio.

Term of officio of members

- (1) The term of officio of a member, other than an ex officio member, shall be,-
 - (a) in case of appointment under clause (e) or clause (f) of sub-section (2) of section 7, three years: 1[xxx]
 - ²[PROVIDED that the term of office of a member elected under clause (f) of sub-section (2) of section 7 shall come to an end as soon as the member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the House of the People, or the Deputy Chairman of the Council of States or Ceases to be a member of the House from which he was elected; and]
 - (b) in case of appointment under clause (g) of the said sub-section, one year.
- If, a casual vacancy occurs in the office of any members, whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, such vacancy shall be filled by the Central Government by making a fresh appointment and the member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.
- The Vice-Chairman shall perform such functions as may be assigned to him by the Chairman from time to time.
- The procedure to be followed by the members in the discharge of their functions shall be such as may be prescribed.

Meetings of the Board

- (1) The Board shall meet at such time and place, and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at such meetings) as may be provided by regulations: PROVIDED that the Board shall meet at least once in six months.
- (2) The chairman and in his absence the Vice-Chairman shall prescribed at the meetings of the Board.
- (3) If for any reason the Chairman or the Vice-Chairman is unable to attend any meeting of the Board, any other member chosen by the members present at the meeting shall preside at the meeting.
- (4) All questions which come up before any meeting of the Board shall be decided by a majority of the votes of the members present and voting, and in the event of an equality of votes, the Chairman, or in his absence, the person presiding,, shall have and exercise a second or casting vote.
- (5) Members other than ex officio members shall receive such allowances, if any, from the Board as may be prescribed.

10. Vacancies, etc, not to invalidate proceedings of the Board

SECTION 14

No act or proceeding of the Board shall be invalid merely by reason of -

- (a) any vacancy in or any defect in the constitution of, the Board, or
- (b) any defect in the appointment of a person acting as a member of the Board: or
- (c) any irregularity in the procedure of the Board not affecting the merits of the case.

11. Temporary association of persons with the Board for particular purposes

- (1) The Board may associate with itself, in such manner and for such purposes as may be determined by regulations any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.
- (2) A person associated with it by the Board under sub-section (1) for any purpose shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the Board and shall not be a member for any other purpose.

12. Appointment of officers and other employees of the Board

(1) For the purpose of enabling it efficiently to discharge its functions under this Act, the Board may, subject to such regulations as may be made in this behalf, appoint (whether on deputation or otherwise) such number of officers and other employees as it may consider necessary;

PROVIDED that the appointment of such category of officers, as may be specified in such regulations, shall be subject to the approval of the Central Government.

(2) Every officer or other employee appointed by the Board shall be subject to such conditions of service and shall be entitled to such remuneration as may be specified in the regulations.

13. Authentication of orders and other instruments of the Board

All order and decisions of the Board shall be authenticated by the signature of the Chairman or any other member authorized by the Board in this behalf, and all other instruments issued by the Board shall be authenticated by the signature of the Member-Secretary or any other officer of the Board authorized in like manner in this behalf.

14. Disqualifications for appointment as member

A person shall be disqualified for being appointed as a member if, he-

- (a) has been convicted and sentenced to imprisonment for an offence which, in the opinion of the Central Government, involves moral turpitude; or
- (b) is an undischarged insolvent; or
- (c) is of unsound mind and stands so declared by a competent court; or
- (d) has, been removed or dismissed from the service of the Government or a Corporation owned or controlled by the Government; or
- (e) has, in the opinion of the Central Government, such financial or other interest in the Board as is likely to affect prejudicially the discharge by him of his functions as a member; or
- ¹[(f) has, in the opinion of the Central Government, been associated with the use or promotion of pre-natal diagnostic technique for determination of sex or with any sex selection technique.]

^{1.} Word "and" omitted vide Act 32 of 2001

^{2.} Provisio inserted, ibid.

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

(2)Every application for registration under sub-section (1) shall be made to the Appropriate Authority in such form and in such manner and shall be accompanied by such fees as may be prescribed.

(3) Every Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic engaged, either partly of exclusively, in counseling or conducting pre-natal diagnostic techniques for any of the purposes mentioned in section 4, immediately before the commencement of this Act, shall apply for registration within sixty days from the date of such commencement.

(4) Subject to the provisions of section 6, every Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic engaged in counseling or conducting prenatal diagnostic techniques shall cease to conduct any such counseling or technique on the expiry of six months from the date of commencement of this Act unless such Centre, Laboratory or Clinic has applied for registration and is so registered separately or jointly or till such application is disposed of, whichever is earlier.

(5) No Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall be registered under this Act unless the Appropriate Authority is satisfied that such Centre, Laboratory or Clinic is in a position to provide such facilities, maintain such equipment and standards as may be prescribed.

19. Certificate of registration

(1) The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements of this Act and the rules made thereunder and having regard to the advice of the Advisory Committee in this behalf, grant a certificate of registration in the prescribed form jointly or separately to the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, as the case may be.

(2) If, after the inquiry 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 this Act or the rules, it shall, for reasons to be recorded in

writing, reject the application for registration.

(3) Every certificate of registration shall be renewed in such manner and

after such period and on payment of such fees as may be prescribed.

(4) The certificate of registration shall be displayed by the registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic in a conspicuous place at its place of business.

20. Cancellation or suspension of registration

- (1) The Appropriate Authority may *suo moto*, or on complaint, issue a notice to the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic to show cause why its registration should not be suspended for cancelled for the reasons mentioned in the notice.
- (2) If, after giving a reasonable opportunity of being heard to the Genetic Counselling Cenre, Genetic Laboratory or Genetic Clinic and having regard to the advice of the Advisory Committee, the Appropriate Authority is satisfied that there has been a breach of the provisions of this Act or the rules, it may, without prejudice to any criminal action that it may take against such Centre, Laboratory or Clinic, suspend its registration for such period as it may think for or cancel its registration, as the case may be.
- (3) Notwithstanding anything contained in sub-sections (1) and (2), if the Appropriate Authority is of the opinion that it is necessary or expedient so to do in the public interest, it may, for reason to be recorded in wrinting, suspend the registration of any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic without issuing any such notice referred to in sub-section (1).

(c) Secretaries or Commissioner in charge of Departments of Women and Child Development, Social welfare, Law and Indian System of Medicines and Homoeopathy, ex officio, or their representatives;

(d) Director of Health and Family Welfare or Indian System of Medicines and Homoeopathy of the State Government, ex officio;

- (e) three women members of Legislative Assembly or Legislative Council;
- (f) ten members to be appointed by the State Government out of which two each shall be from the following categories:-
- (i) eminent social scientists and legal experts;
- (ii) eminent women activities from non-governmental organizations or otherwise;
- (iii) eminent gynacecologist and obstetricians or experts of stri-roga or prasuti-tantra;
- (iv) eminent paediatricians or medical geneticists;

(v) eminent radiologists or sonologists;

SECTION 17

- (g) An officer not below the rank of Joint Director in charge of Family Welfare, who shall be the Member Secretary, ex officio
- (3) The State Board shall meet at least once in four months.
- (4) The term of office of a member, other than an ex-officio member, shall be three years.

(5) If a vacancy occurs in the office of any member other than an ex-

officio member, it shall be filled by making fresh appointment.

- (6) If a member of the Legislative Assembly or member of the Legislative Council who is a member of the State Board, becomes Minister or Speaker or Deputy Speaker of the Legislative Assembly or Chairperson or Deputy Chairperson of the Legislative Council, he shall cease to be a member of the State Board.
- (7) One-third of the total number of members of the State Board shall constitute the quorum.
- (8) The State Board may co-opt a member as and when required, provided that the number of co-opted members does not exceed one-third of the total strength of the State Board.
- (9) The co-opted members shall have the same powers and functions as other members, except the right to vote and shall abide by the rules and regulations.
- (10) In respect of matters not specified in this section, the State Board shall follow procedures and conditions as are applicable to the Board.]

CHAPTER V

APPROPRIATE AUTHORITY AND ADVISORY COMMITTEE

17. Appropriate Authority and Advisory Committee

- (1) The Central Government shall appoint, by notification in the Official, Gazette, one or more Appropriate Authorities for each of the Union territories for the purpose of this Act.
- (2) The State Government shall appoint, by notification in the Official Gazette, one or ore Appropriate Authorities for the whole or part of the State for the purposes of this Act having regard to the intensity of the problem of pre-natal sex determination leading to female foeticide.

- (3) The officers appointed as Appropriate Authorities under subsection (1) or sub-section (2) shall be,-
- ¹[(a) when appointed for the whole of the State or the Union territory, consisting of the following three members:-
 - (i) an officer of or above the rank of the Joint Director of Health and Family Welfare-Chairperson;
 - an eminent woman representing women's organization; and
 - (iii) an officer of Law Department of the State or the Union territory concerned:
 - PROVIDED that it shall be the duty of the State or the Union territory concerned to constitute multi-member State or Union territory level Appropriate Authority within three months of the coming into force of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002; PRÖVIDED FURTHER that any vacancy occurring therein shall be filled within three months of the occurrence;
 - when appointed for any part of the State or the Union territory, of such other rank as the State Government or the Central Government, as the case may be, deem fit.
 - the Appropriate Authority shall have the following functions, namely:-
 - to grant, suspend or cancel registration of Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic;
 - to enforce standards prescribed for the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic;
 - to investigate complaints of breach of the provisions of this Act or the rules made thereunder and take immediate action;
 - to seek and consider the advice of the Advisory Committee, constituted under sub-section (5), on application for registration and on complaints for suspension or cancellation of registration;
 - ²[(e) to take appropriate legal action against the use of any sex selection technique by any person at any place, suo motu or brought to its notice and also to initiate independent investigations in such matter;
 - to create public awareness against the practice of sex selection or pre-natal determination of sex;
 - to supervise the implementation of the provisions of the Act and rules;
 - to recommend to the Board and State Board modifications required in the rules in accordance with changes in technology or social conditions;
 - to take action on the recommendation of the Advisory Committee made after investigation of complaint for suspension or cancellation of registration.]
 - The Central Government or the State Government, as the case may be, shall constitute an Advisory Committee for each Appropriate Authority to aid and advise the

Appropriate Authority in the discharge of its functions, and shall appoint one of the members of the Advisory Committee to be its Chairman.

(6) The Advisory Committee shall consist of -

(a) three medical experts from amongst gynaecologist, obstetricians, paediatricians and medical geneticist;

one legal expert;

SECTION 18

(c) one officer to represent the department dealing with information and publicity of the State Government or the Union Territory, as the case any be;

(d) Three eminent social workers of whom not less than one shall be from amongst representatives of women's organizations.

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

(8) The Advisory Committee may meet as when it thinks fit or on the request of the Appropriate Authority for consideration of any application for registration or any complaint for suspension or cancellation of registration and to give advice thereon:

PROVIDED that the period intervening between any two meetings

shall not exceed the prescribed period.

(9) 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 in the discharge of its functions shall be such as may be prescribed.

²[17A. Power of Appropriate Authorities

The Appropriate Authority shall have the powers in respect of the following matters, namely:-

- (a) Summoning of any person who is in possession of any information relating to violation of the provisions of this Act or the rules made thereunder;
- Production of any document or material object relating to clause (a);
- Issuing search warrant for any place suspected to be indulging in sex selection techniques or pre-natal sex determination; and
- (d) Any other matter which may be prescribed.]

CHAPTER VI

REGISTRATION OF GENETIC COUNSELLING CENTRES, GENETIC LABORATORIES AND GENETIC CLINICS

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

¹[(1) No person shall open any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, including clinic, laboratory or centre having ultrasound or imaging machine or scanner or any other technology capable of undertaking determination of sex of foetus and sex selection, or render services to any of them, after the commencement of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002 unless such Centre, Laboratory or Clinic is duly registered under the Act.]

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

^{2.} Insetted, ibid.

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

^{2.} Inserted, ibid.

(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.

¹[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 Prenatal 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-
 - ¹[(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 subsection (4) of section 8;
 - (v) Allowances for members other than ex officio members admissible under sub-section (5) of section 9;
 - ¹[(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 reposts 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

SECTION 23

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

OFENCES AND PENALTIES

¹[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 preconception 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 for 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.

¹[(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 gubes great affects.

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-sectio (3) shall not apply to the woman who was compelled to undergo

such diagnostic techniques or such selection.]

¹[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 abetment 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 noting 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.

Exaplanation: For the purpose of this section,-

- (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

SECTION 30

(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 ¹[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 VIIIMISCELLANEOUS

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.

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

^{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)
 - Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.
 - Inverted microscope
 - Incubator and oven.
 - Carbon dioxide incubator or closed system with 5% CO₃ atmosphere.
 - Autoclave
 - Refrigerator.
 - Water bath.
 - Centrifuge
 - Eletrophoresis 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.
 - Refrigerators (4 degree and minus 20 degree Centigrade).
 - Water bath.
 - Micro centrifuge.
 - Electrophoresis apparatus and power supply.
 - 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.

- 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;
- 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

SECTION 34

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 therunder to provide for-

- 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;
- the manner in which a person may be temporarily associated with the Board under sub-section (1) of section 11;
- 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 intwo 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 from 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

- ¹[(1) These Rules may be called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rule, 1966.]
- (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)2;
- (b) "employee" means a person working in or employed by a 3[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres,] and includes those working on parttime, contractual, consultancy, honorary or on any other basis;
- (c) "From" means Form appended to these rules;
- $^{4}[(d) xxx]$
- (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.
- ⁵[(g) "Mobile Medical Unit" means a mobile vehicle which provides specialized facilities for the patients, requiring basic specialist services and

RULE 3

THE PRE-CONCEPTION AND PRE-NATAL ACT, 1994 23

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.]

¹[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 prenatal 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% CO₂ atmosphere.
 - 6) Autoclave
 - (7) Refrigerator.
 - (8) Water bath
 - (9) Centrifuge.
 - (10) Vortex mixer.
 - (11) Magnetic strirrer.
 - (12) pH meter

^{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.

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

^{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.

¹[5. Application Fee

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

(a) ²[Rupees Twenty-five thousand] for Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre.

(b) ³[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 resubmission of the application by the applicant for the same body within 90 days of rejection PROVIDED FURTHER that any subsequent application shall be accompanied with the prescribed fee. Application fee once paid will not be refunded.

(2) The application fee shall be paid by a demand draft drawn in favour of the Appropriate Authority, on any scheduled bank payable at the 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 4[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.

- (16) U.V IIIuminator with photographic attachment or other documentation system.
- (17) Precision micropipettes.

RULE 3A

(18) Such other equipmets 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.]
- ¹[(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.]

²[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 Cinic, Ultrasound Clinic, Imaging Centre or any other body or person unless such Centre, Laboratory, Clinic, body or person is registered under the Act.

^{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.

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

^{1.} Inserted vide GSR 418(E), dt. 4-6-2012, w.e.f. 5-6-2002

^{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 Clini, 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.]

¹[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

- Referral of complicated cases;
- Early detection of TB, Malaria, Leprosy, Kala-Azar and other locally endemic communicable diseases and no-communicable disease such as hypertension diabetes, cataract cases etc;
- Minor surgical procedures and suturing;
- Specialist services such as O and G Specialist, Paediatrician and Physician:

(ii) Reproductive and Child Health Services

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

(iii) Family Planning Services

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

RULE 4

- (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.
 - 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 ¹[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Cinic and Imaging Centres

²[(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;
- 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
- ³[(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.
- 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

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

RULE 7

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.

¹[(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

²[(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 3 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.

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

- ¹[(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;
 - 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 of 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 2[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 2[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 2[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.

Validity of registration

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

^{1.} Substituted vide GSR 426(E), dt. 31-5-2011, w.e.f. 2-6-2011. Prior to substitution, sub-section (2)

[&]quot;(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."

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

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

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

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 1[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

²[(1) Every Genetic Counselling Centre, Genetic Laboratory, 3[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 prenatal 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.

²[(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 3[Genetic Clinic including a Mobile Genetic Clinic], in respect of each man or woman subjected to any prenatal diagnostic procedure/technique/test, shall be as specified in Form F.

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

(6) All case related records, forms of consent, laboratory results, microscopic pictures, sonographic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres] for a period of two years form 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 lagal 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.

RULE 11

(7) In case the ¹[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. 2[(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 5th day of the following month to the concerned Appropriate Authority.]

10. Conditions for conducting pre-natal diagnostic procedures

³[(1) Before conducting pre implantation genetic diagnosis, or any prenatal diagnostic technique/test/procedure such as amniocentesis, chorinic 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 form 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.

²[(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.

³[11. Facilities for inspection

(1) Every Genetic Couselling 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

Substituted for "Genetic Couselling 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.

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.

completed 4 weeks' training in genetic counseling. SCHEDULE II

(3) Paediatrician with 6 months' experience in genetic counseling, or having

[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, 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% CO₂ 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 ¹[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 covey it to a facility for analysis or test, if analysis or test required:

PROVIDED that the refrigerator or other equipment used by the ¹[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 ¹[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 maymake arrangements, by way of mounting a guard or sealing of the premises of the ¹[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 ¹[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 ²[atleast 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.

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

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 ¹[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 ¹[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 1[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.
- ²[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 fotus except for the purposes specified in sub-section (2) of section 4 of the Act;

- (iv) not conduct or cause to be conducted or aid in conducting by himself or through any other person any techniques or test or procedure under the Act at a place other than a place registered under the Act/these Rules;
- (v) ensure that no provision of the Act and these Rules are violated in any manner;
- (vi) ensure that the person, conducting any techniques, test or procedure leading to detection of sex of foetus for purposes not covered under section 4(2) of the Act or selection of sex before or after conception, is informed that such procedures lead to violation of the Act and these Rules which are punishable offences;
- (vii) help the law enforcing agencies in 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.]

¹[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 subrules (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 form making such appeal.]

²[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.

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.

^{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	o all employees of
the Genetic Counsellin	g Centre/Genetic Laboratory	/Genetic Člinic/
ultrasound clinic /imagir	ng centre in respect of which reg	istration is sough
and to ensure that Act ar	nd Rules are fully complied with	
Date:	3 1	
Place:	(
	Name, designation and sign	ature of the persor
	authorized to sign on behalf	
	to be registered	O

[SEAL OF THE ORGANISATION SOUGHT TO BE REGISTERED]

ACKNOWLEDGEMENT

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

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

OI

* 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]

¹[FORM B]

[Refer rules 6(2), 6(5) and 8(2)] CERTIFICATE OF REGISTRATION

(To be issued in duplicate)

- (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 cathether 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.

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

(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.]

¹[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 io 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.

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

FORM A

- (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 Centre1 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 regis	stered) hereby declare that I have
read and understood the	he Pre-natal Diagnostic Techniques (Regulation and
Prevention of Misuse)	Act, 1994 (57 of 1994) ² and the Pre-natal Diagnostic

Techniques (Regulation and Prevention of Misuse) Rules, 1996.³

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

Strike out whichever is not applicable or not necessary. All enclosure are to be authenticated by signature of the applicant.

Read as "The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection)
 Act. 1994 (57 of 1994)"
 Read as "The Pre-concept and Pre-natal Diagnostic (Prohibition of Sex Selection) Rules, 1996"

(vi)	Sex	linked	disorde

- (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: Date:]

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

¹[FORM F

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

(New amended on 4th February, 2014 notified on 31th 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:
^	Designation Nie (Lie ton DC & DNIDT Ast 1004)

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

(b) Number of living Daughter with age of each living daughter (in years or months):

5.	Husba	nd's/	Wife's,	/Father's,	/Motl	her's	s Name	: ڊ
_	- 11							

6.	Full postal	address	of the	patient	with	contact	Number	', if
	any:							
	3							

7.	(a) Referr Counselli	ed by ng Ce	(full ntre)	name :	and	address	of	Doctor(s) Ge	eneti

- 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 Clini c*/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)

FromTo......
Signature name and designation of the Appropriate Authority
SEAL

Date:

FORM C

¹**[FORM C]**[Refer rules 6(3), 6(5) and 8(3)]
[A PDI A TION FOR CRANIT / PENIES

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.]

¹[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. radiogical, 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 advised2
 - (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) Preimplation 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 Geneticst/Gynaecologist/Paediatrician administering Genetic Counseling.

Place : Date :]

FORM E

¹[FORM E

[Refer rule 9(3)

MAINTENANCE OF RECORDS BY GENETIC LABORATORY

- Name and address of Genetic Laboratory
- 2. Registration No.
- 3. Patient's Name
- 4. Ag
- 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. Previsous 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

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I,	me of the pregnant woma est), I have neither detect	raphy/image scani in or the person und	ng on Ms./ lergoing pre
	Name in Capitals, Registr aecologist/Radiologist/I Co		Practitioner
procedures in my own interest deformity/disorder) in the ch I undertake not to termin test conducted show the abser I understand that the sex I understand that bread prescribed in the Pre-natal Diag Act, 1994 (57 of 1994) ² and rule Date: Place:	at I have been explained furth agenostic procedures. Oreimplantation / pre-nato find out the possibility ild I am carrying, late the pregnancy if the process of disease / deformity, of the foetus will not be a hof this undertaking with the prostic Techniques (Regules framed thereunder.	Age	e effects and nique/test/ (i.e. disease/ 'technique/ o penalty as on of Misuse) nant woman
Relationship			
-	Na Number of Gyna	me, Signature and lecologist / Medical ogist / Paeditrician the Clinic/Centre,	Registration Geneticist/ Director of
Date:	Name, Addı	ress and Registratio Genetic Clinic	

FORM F THE PRE-CONCEPTION AND PRE-NATAL...... RULES, 1996 45

(*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-referred does not mean a client coming to a clinic and requesting for the test or the relative/s requesting for the test of a pragnant 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:_____
- i. To diagnose intra-uterine and/or ectopic pregnancy and confirm viability.
- i. Estimation of gestational age (dating).
- iii. Detection of number of fetuses and their chorionicity.
- iv. Suspected pregnancy with IUCD in-situ or suspected pergnancy 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 amenorrhea.
- ix. Any suspected adenexal or uterine pathology/abnormality.
- x. Detection of chromosomal abnormalities, fetal structural defects and other abnormalities and their follow-up.
- xi. To evaluate fetal presentation and position.
- xii. Assessment of liqour amnii.
- xii. Preterm labour / preterm premature rupture of membrances.
- xiv. Evaluation of placental position, thickness, grading and abonormalities (placenta praevia, retro placental hemorrhage, abnormal adherence etc.)
- xv. Evaluation of umbilical cord-presentation, insertion, nuchal encercliment, 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 theraputic 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.

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

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

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	xxii. Medical/surgical conditions xxiii. Research/scientific studies in								
	, out the season of the season	2000 82 220 220 220 20 20 20 20 20 20 20 20 20							
11.	Procedures carried out (Non-Invasive) (Put a "Tick" on the appropriate procedure								
	i. Ultrasound								
	(Important Note: Ultrasound is not indicated/advised/performed t								
	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. 14.	Date of which procedures carried out:								
14.	Result on which procedures carried	າແ:							
15.	The result of pre-natal diagnostic pre	 ocedures was conveyed to	-						
10.	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								
	,								
ъ.	N	17 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1							
Date :		and Registration Number with Seal of							
Place:		diologist/Registered Medical Practition performing Diagnostic Procedu	me						
r lace.		performing Diagnostic Flocedu	14						
SECT	$\Pi\mathbf{ON}\mathbf{C}$: To be filled for performing invas	ive Procedures/Tests only							
17.		Name of the doctor/s performing the procedure/s:							
18.	History of genetic/medical disease in	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, ultrasonogrphy etc.								
	specify)								
19.	Indication/s for the diagnosis procedure ("Tick" on appropriate basis of								
	indication/s)								
	A. Previous child/chidren with:	/// 3.5 . 1 1· 1· 1							
	(i) Chromosomal disorders	(ii) Metabolic disorders							
	(iii)Congenital anomaly	(iv) Mental Disability							
	(v) Haemoglobinopathy(vii)Single gene disorder	(vi)Sex lined disorders (viii) Any other (specify)							
	(vn)omgre gene cusorder	(viii) Arity outer (specify)							
	B. Advanced maternal age (35 year	(2							
	C. Mother/father/sibling has genetic disease (specify)								
	D. Other (specify)								
	D. Other (specify)								

Date on which consent of pregnant woman / person was obtained in Form G

Invasive procedures carried out ("Tick" on appropriate basis of indication/s)

(ii) Chorionic Villi aspiration

(iv) Cordocentesis

prescribed in PC & PNDT Act, 1994_

Any complication/s of invasive procedure (specify):___

(i) Amniocentesis

(iii) Fetal biopsy(v) Any other (specify)

23.	Additional tosts	recommended (Place mont	Hio	n if annlicah	10).		
25.	(i) Chromoson				Biochemica			
	(iii) Molecular s					ation gender		
	(111) 1110100011111		(4-1	٠,	diagnosis	arion Bornaci		
	(v) Any other (s	specify)						
24.	Result of the procedures/Tests carried out (report in brief of the invasive tests/							
	procedures carried out)							
25.	Date on which t	orocedures carrie	ed out:					
26.	The result of pre	of pre-natal diagnostic procedures was conveyed to						
	on							
27.	Any indication for MTP as per the abnormality detected in the diagnostic							
		ts:						
Date:	Name, Signature and Registration Number with Seal of the							
		Gynaecologist/Radiologist/Registered Medical Practitioner						
			p	er	forming Dia	gnostic Procedure	e/s	
	n D: Declaration				C PPE MA			
DECI	LARATION OF					TAL DIAGNOST	IC	
		গৰ্ভপূৰ্বক পৰীক্ষা/'	PROCEDUI প্রকৃতি গ্রহণক	KE	! কি হোসলো			
I Mrc	./Mr		ग्रेशा ७ ध्यस्यायः		doclaro	that by undergo	inc	
1, 11113	., m Pre-	natla diagnostic	test/proced	d11	re. I do not v	vant to know the	ււը Ses	
of mv	foetus							
oy	মই শ্রী/শ্রীমতী				रृष्ट	গাষণা কৰো যে গৰ্ভপ	র্বব	
পৰীক্ষা	/পদ্ধতি গ্ৰহণৰ দ্বাৰা	ব্ৰুণৰ লিঙ্গ জানিবলৈ	া বিচৰা নাই।			যাষণা কৰো যে গৰ্ভপূ	`	
Date:			,					
		Signature	/Thumb im	ιpi	ression of the	e person undergo	ing	
		-	the Pre	e-r	natal Diagnos	stic Test/Proced	ure	
তাং-			গৰী মহিলা/ব্য	र्जि	ক্ৰৰ স্বাক্ষৰ/বুঢ়া	আঙুলিৰ টিপচহী বা	ছাগ	
In Cas	se of thumb Impr	ession:						
	ঙুলিৰ টিপচহী বা ছাগ							
	ified by (Name)					Sex		
চিনাক্ত	কাৰীৰ নামঃ				বয়স	লিঙ্গ	—	
Relati	on (if any):		Address	&	Contact No			
 সন্ধন (যিদি হয়) ঃ		ঠিকনা ও ফ	Tte	াযোগৰ ফোন ন	16		
1 4 41 (11.		1 \		
Signa	ture of a person a	ittesting thumb i	mpression:			Date		
স্বাৰ্ক্ষৰ	ঃ (চিনাক্তকাৰীৰ) _					তাং		

THE PRE-CONCEPTION AND PRE-NATAL...... RULES, 1996 47

FORM G

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 fir, 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 from 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 be 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.

1FORM H

[Refer rule 9(5)]

MAINTENANCE OF PERMANENT RECORD OF APPLICATIONS FOR GRANT/ RJECTION OF REGISTRATION UNDER THE PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) ACT. 1994²

- 1. SlNo.
- 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.

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

THE PRE-NATAL DIAGNOSTIC THECHNIQUES (REGULATION AND PREVENTION OF MISUSE) ADVISORY COMMITTEES0 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 Musise) Act, 1994 (57 of 1994);
- (b) "Advisory Committee" means and 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 a 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 un discharged insolvent; or

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

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

- (c) is not unsound 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 form 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.