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List of Amending Acts

1. Pre-natal Diagnostic Techniques (Regulation and preventions of Misuse)
Amendment Act, 2001 (32 of 2001)
2. Pre-natal diagnostic Techniques (regulations and preventions of Misuse)
Amendment Act, 2002 (14 of 2003)

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

[20th September, 1994]

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 purpose 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 Republic of India as follows:-

Statement of Objects and Reasons-It is proposed 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. Legislation is required to regulate the use of such techniques and to provide deterrent punishment to stop such inhuman act.

(2)The Bill, inter alia, provides for:-

- (i) 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 techniques 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) Punishment for violation of the provisions of the proposed legislation.

Amendment Act 32 of 2001-Statement of Objects and Reasons- The Pre-natal Diagnostic Techniques (regulation and Prevention of Misuse) Act, 1994 and the Rules framed there under came into force with effect from 1st January, 1996. The Act Provides for disorders, chromosomal abnormalities, certain congenital malformation of sex linked disorders and for the prevention of the misuse of such techniques for the purpose of prenatal sex determination leading to female foeticide, and for matters connected therewith or incidental thereto.

2. A Central Supervisory Board has been constituted under section 7 of the Act which includes three women Members of Parliament. At present, there is no provision in the Act for deemed termination of membership of a Member of Parliament on her subsequent appointment as a Minister or Minister of State or Deputy Minister or the Speaker or Deputy Speaker , Lok Sabha or Deputy Chairman, Rajya Sabha. It is proposed to provide that consequent upon a Member of Parliament becoming a Minister of state or

1. Substituted by Act 14 of 2003, S.2 for long title (w.e.f. 14-2-2003). Prior to its substitution, long title read as under: -
“An Act to provide for the regulation of the use of pre-natal diagnostic techniques for the purpose of detecting genetic or metabolic disorders or chromosomal abnormalities or certain condential mal-formations or sex linked disorders and for the prevention of the misuse of such techniques for the purpose od pre-natal sex determination leading to female foeticide; and , for matters connected there with or incidental thereto.

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2. Deputy Minister or the Speaker or Deputy Speaker of the House of the People, or the Deputy Chairman of the Council of States, her membership of that body shall stand terminated.
3. The Bill seeks to achieve the above object by amending the relevant provisions of the Act.

Amendment Act 14 of 2003-statement of Objects and Reasons – The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 seeks to prohibit pre-natal diagnostic techniques for determination of sex of the foetus leading to female foeticide. During recent years, certain inadequacies and practical difficulties in the administration of the said Act have come to the notice of the Government, which has necessitated amendments in the said Act.

2. The Pre-natal diagnostic techniques like amniocentesis and sonography are useful for the detection of genetic or chromosomal disorders or congenital malformations or sex linked disorders, etc. However, the amniocentesis and sonography are being used on a large scale to detect the sex of the foetus and to terminate the pregnancy of the unborn child if found to be female. Techniques are also being developed to select the sex of child before conception. These practice and techniques are considered discriminatory to the female sex and not conducive to the dignity of the women.

3. The proliferation of the technologies mentioned above may, in future, precipitate a catastrophe, in the form of severe imbalance in male-female ratio. The State is also duty bound to intervene in such matters to uphold the welfare of the society, especially of the women and children. It is, therefore, necessary to enact and implement in letter and spirit a legislation to ban the pre-conception sex selection techniques and the misuse of pre-natal diagnostic techniques for sex-selective abortions and to provide for the regulation of such abortions. Such a law is also needed to uphold medical ethics and initiate the process of regulation of medical technology in the larger interests of the society.

4. Accordingly, it is proposed to amend the aforesaid Act with a view to banning the use of both sex selection techniques prior to conceptions as well as the misuse of pre-natal diagnostic techniques for sex selective abortions and to regulate such techniques with a view to ensuring their scientific use for which they are intended.

5. The bill seek to achieve the aforesaid objects.

CHAPTER I
PRELIMINARY

1. Short title, extent and commencement - (1) This Act may be called ²[THE PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION)] ACT, 1994.

(2) It shall extent 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 fertilization until birth including extra embryonic membranes as well as the embryo or foetus:

2. Substituted by Act 14 of 2003, S.3, for “THE PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE)”(w.e.f.14-2-2003).

3. Brought into force on 1st January, 1996.

4. Inserted by Act 14 of 2003, S.4(w.e.f.14-2-2003)

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(bb) "embryo" means a developing human organism after fertilization 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 fertilization or creation (excluding any time in which its development has been suspended) and ending at the birth;)

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

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

⁵[Explanation – For the purpose of this clause, "Genetic Clinic" includes a vehicle, where ultrasound machine or imaging 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.

⁶[Explanation – For the purpose 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) "Gynecologist" means a person who possesses a post-graduate qualification in gynecology and obstetrics

⁷[(g) "medical geneticist" includes a person who possesses a degree or diploma in genetic science in the field of sex selection and pre-natal diagnostic techniques or has experience of not less than two years in any of these fields after obtaining –

(i) Any one of the medical qualification recognized under the Indian Medical Council Act, 1956 (102 of 1956); or

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

(h) "paediatrician" means a person who possesses a post-graduate qualification in paediatrics.

5. Added by Act 14 of 2003, S.4 (w.e.f. 14.-2-2003)

6. Inserted by Act 14 of 2003, S.4 (w.e.f 14-2-2003)

7. Substituted by Act 14 of 2003, S.4, for CI. (g) (w.e.f. 14.2.2003) Prior to its substitution,

CI. (g) read as under: - "(g) "Medical geneticist" in the field of pre-natal diagnostic techniques or has experience of not less than two years in such field after obtaining –

(i) Any one of the medical qualifications recognized under the Indian Medical council Act, 1956 (102 of 1956); or

(ii) A post-graduate decree in biological sciences;"

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⁸[(i) “pre-natal diagnostic procedures means all gynaecological or obstetrical or medical procedures such as ultrasonography, foetoscopy, taking or removing samples of amniotic fluid, chorionic villi, 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 procedures and pre-natal diagnostic tests;

⁹[(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 clause (h) of section 2 of the Indian Medical Council Act, 1956 (102 of 1956), and whose name has been entered in a State Medical Register;

(n) “Regulations” means regulations framed by the Board under this Act.

¹⁰[(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 Council Act, 1956 (102 of 1956) or who possesses a post-graduate qualification in ultrasonography or imaging techniques or radiology;

(q) “State Board” means a State Supervisory Board or a Union Territory Supervisory Board constituted under section 16-A

(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 the Constitution.].

**CHAPTER II
REGULATION OF GENETIC COUNSELLING CENTERS, GENETIC
LABORATORIES AND GENETIC CLINICS**

3. Regulation of Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics – On and from the commencement of this Act, -

8. Substituted by Act 14 of 2003, S. 4, for CI.(i) (w.e.f.14-2-2003). Prior to its substitution, CI.(i) read as under: - “(i) “pre-natal diagnostic procedures” means all gynaecological or obstetrical or medical procedures such as ultrasonography, foetoscopy, taking or removing samples of amniotic fluid, chorionic villi, blood or any tissue of a pregnant woman for being sent to a Genetic Laboratory or Genetic Clinic for conducting pre-natal diagnostic test;”

9. Substituted by Act 14 of 2003, S.4, for CI. (k) (w.e.f. 14-2-2003). Prior to its substitution, CI. (k) Read as under:- “(k) “pre-natal diagnostic test” means ultrasonography or any test or analysis of amniotic fluid, chromosomal abnormalities or congenital anomalies or haemoglobinopathies or sex-linked diseases;”

10. Inserted by Act 14 of 2004, S.4 (w.e.f. 14-2-2003)

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(PROHIBITION OF SEX SELECTION) ACT, 1994**

(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;

¹¹[(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 qualification as may be prescribed;]

(3)no medical geneticist , gynaecologist, paediatrician, registered medical practioner 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 than a place registered under this Act.

¹²[**3-A. Prohibition of sex selection** – No person, including a specialist or a team of specialists in the filed 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, concepts, fluid or gametes derived from either or both of them

3-B. 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

Regulation of pre-natal diagnostic 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 expect for the purposes specified in clause (2) and after satisfying any of the conditions specified in clause (3);
- (2) no pre-natal diagnostic techniques shall be conducted expect for the purposes of detection of any of the following abnormalities, namely: -
 - (i) Chromosomal abnormalities;
 - (ii) Genetic metabolic diseases;
 - (iii) Heamoglobinopathies;
 - (iv) Sex-linked genetic diseases;
 - (v) Congential anomalies;
 - (vi) Any other abnormalities or diseases as may be specified by the Central supervisory Board;

11. Substituted by Act 14 of 2003, S.5, for CI. (2) (w.e.f. 14-2-2003). Prior to its substitution, CI. (2) read as under: - “(2) no genetic Counselling Centre, Genetic Laboratory or Genetic Clinics Shall employ or cause to be employed any person who does not possess the prescribed qualifications;”

12. Inserted by Act 14 of 2003, S.6 (w.e.f. 14-2-2003).

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¹³[(3) No pre-natal diagnostic techniques shall be used or conducted unless the persons 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;

The pregnant woman had been exposed to potentially teratogenic agents such as, drugs, radiation, infection or chemicals;

(iii) The pregnant woman or her souse has a family history of mental retardation or physical deformallities such as, spasticity or any other genetic disease;

(iv) 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 provisions of section 5 or selection 6 unless contrary is provided 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 expect for the purpose 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.]

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 procedure to the pregnant woman concerned;

(b) He has obtained in the prescribed from 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.

13. substitute by Act 14 of 2003, S.7, for Cls. (3) and (4) (w.e.f. 14-2-2003). Prior to their substitution, Cls. (3) and (4) read as under: - “(3) no pre-natal diagnostic techniques shall be used or conducted unless the person qualified to do so is satisfied that any of the following conditions are fulfilled, namely: -

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

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

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

(iv) the pregnant woman has a family history of mental retardation or physical deformities such as spasticity or any other genetic disease;

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

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

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¹⁴[(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 from the commencement of this Act, -

(a) no Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic shall conduct or cause to be conducted 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 conduct any pre-natal diagnostic techniques including ultrasonography for the purpose of determining the sex of a foetus.

¹⁵[(c) no person shall, by whatever means, cause or allow to be caused selection of sex before or after conception.]

**CHAPTER IV
CENTRAL CUPERVISORY BOARD**

7. Constitution of central Supervisory Board - (1) The Central Government shall constitute a 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*;

¹⁶[(c) three members to be appointed by the Central Government to represent the Ministries of Central; Government in charge of Woman and Child Development, Department of Legal Affairs pr 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;

14. Substituted by Act 14 of 2003, S.8, for sub-S. (2) (w.e.f. 14.2.2003). Prior to its substitution, sub-S. (2) read as under: - “(2) No person conducting pre-natal diagnostic procedures shall communicate to the pregnant woman concerned or her relatives the sex of the foetus by words, signs or in any other manner.”

15. Inserted by Act 14 of 2003, S.((w.e.f 14.2.2003).

16. Substituted by Act 14 of 2003, S. 10, for CI. (c) (w.e.f. 14.-2-2003). Prior to its substitution, CI. (c) read as under: - “(c) two members to be appointed by the Central Government to represent the Ministers of Central Government in charge of Woman and child Development and Law and Justice, *ex officio*.”

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- ¹⁷[(ii) eminent gynaecologist and obstetrician or expert of stri-rofa or prasuti-tantra;];
- (iii) eminent paediatricians;
- (iv) eminent social scientists; and
- (v) representatives of women welfare organisations;

(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;

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;

(h) 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*.

8. Term of office of members - (1) the term of office 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 years¹⁸[*]:

¹⁹[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 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 she was elected; and]

(b) In case of appointment under clause (g) of the said Sub-section, one year.

(2) If a casual vacancy occurs in the office of any other members, whether by reasons 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 member appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

(3) The Vice-Chairman shall perform such functions as may be assigned to him by the Chairman from time to time

(4) The procedure to be followed by the members in the discharge of their functions shall be such as may be prescribed

9. 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 the 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.

17. Substituted by Act 14 of 2003, S.10, for sub-Cl. (ii) (w.e.f. 14-2-2003). Prior to its substitution, Sub-Cl. (ii) read as under: - “(ii) eminent Gynecologists and obstetricians;”

18. The word “and” omitted by Act 32 of 2001, S.2 (w.e.f. 3-9-2001).

19. Inserted by Act 32 of 2001, S.2 (w.e.f. 3-9-2001).

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(2) The Chairman and in his absence the vice-chairman shall preside at the meetings of the Board.

(3) If for any reasons 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) Member 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 - 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 purpose as may be determined by regulations, any persons 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 discussion 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 orders and decisions of the Board shall be authenticated by the signature of the Chairman or any other member authorised 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 authorised in like manner in this behalf

14. Disqualification 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

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(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 function as a member, or

²⁰[(f) has in 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.]

15. Eligibility of member for the 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:

²²[**16. Functions of the Board** - The Board shall have the following functions, namely: -

(i) to advise the Central Government on policy matters relating to use of pre-natal diagnostic technique, sex selection technique and against their misuse;

(ii) to review and monitor implementation of the Act and rules made thereunder 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 persons working at Genetic Counselling Centers Genetic Laboratories and Genetic Clinics;

(v) to oversee the performance of various bodies constituted under the Act and take appropriate steps to ensure its proper and effective implementation;

(vi) any other functions as may be prescribed under the Act.]

20. Substituted by Act 14 of 2003, S.11, for C1. (f) (w.e.f. 14-2-2003). Prior to its substitution, C1 (f) read as under: - “(f) has, in the opinion of the Central Government, has been associated with the use or promotion of pre-natal diagnostic technique for determination of sex.”

21. Inserted by Act 14 of 2003, S.12, (w.e.f 14-2-2003).

22. Substituted by ACT 14 of 2003, S.13 for S.16 (w.e.f 14-2-2003). Prior to its substitution, S.16 read as under: - “16 . Functions of the Board - the Board shall have the following functions, namely: -

(i) to advise the Government on policy matters relating to the use of pre-natal diagnostic techniques;

(ii) to review implementation of the Act and the rules made thereunder and recommend changes in the said Act and rules of the Central government;

(iii) to create public awareness against the practice of pre-natal diagnostic determination of sex and female foeticide;

(iv) to lay down code of conduct to be observed by person working at Genetic Counselling Centres, Genetic Laboratories and Genetic Clinics;

(v) any other function as may be specifies under the Act.”

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²³[16-A 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; -

- (i) 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 prescribes 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 Commissioners in charge of Departments 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 women activist from non-governmental organistions or otherwise;
- (ii) eminent women activists from non-governmental organistions or otherwise;
- (iii) eminent gynaecologists and obstetricians or experts of *striroga* or *prasuti-tantra*;
- (iv) eminent paediatricians 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.

(3) The State Board shall meet at least once in four months.

(4) The term of office of member, other than an ex officio member, shall be three years.

(5) if a vacancy occurs in the office of anu member other than an ex officio member, it shall be filed by making fresh appointment.

23. Inserted by act 14 of 2003, S. 14 (w.e.f. 14-2-2003)

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(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, 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 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 more Appropriate Authorities for the whole or part of the State for the purpose of this act having regard to the intensity of the problem of pre-natal sex determination leading to female foetiside.

(3) The officers appointed as Appropriate Authorities under sub-section (1) or sub-section (2) shall be,-

²⁴[(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 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 Preventions of Misuse) Amendment Act, 2002:

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

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

24. Substituted by Act 14 of 2003, S. 15, for C1.(a) (w.e.f. 14-2-2003). Prior to its substitution, Cl. (a) read as under: - "(a) when appointed for the whole of the state or the Union territory, of or above the rank of the Joint Director of Health and Family Welfare; and".

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- (4) The Appropriate Authority shall have the following functions, namely: -
- (a) to grant, suspend or cancel registration of a Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic;
 - (b) to enforce standards prescribed for the Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic
 - (c) to investigate complaints of breach of the provisions of this act or the rules made thereunder and take immediate action; and
 - (d) 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;
 - ²⁵[(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 investigation in such matter;
 - (f) to create public awareness against the practice of sex selection pre-natal determination of sex;
 - (g) to supervise the implementation of the provisions of the Act and rules;
 - (h) to recommend to the Board and State Boards modifications required in the rules in accordance with change 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.]
- (5) 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 function, 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 gynaecologists, obstetricians, paediatricians and medical genetics;
 - (b) one legal expert;
 - (c) one officer to represent the department dealing with information and publicity of the State Government or the Union territory, as the case may be;
 - (d) three eminent social workers of whom not less than one shall be from amongst representatives of women's organisations.
- ²⁶[(7) No person who had been associated with the use or promotion of pre-natal diagnostic technique for determination of sex or sex selection shall be appointed as a member of the Advisory Committee.]

25. Inserted by Act 14 of 2003, S.15 (w.e.f 14-2-2003).

26. Substituted by Act 14 of 2003, S. 15, for sub-S (7) (w.e.f. 14-2-2003). Prior to its substitution, sub-S. (7) read as under: -
(7) No person who, in the opinion of the Central Government or the State Government, as the case may be, has been associated with the use or promotion of pre-natal diagnostic technique for determination of sex shall be appointed as a member of the Advisory Committee.”

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(8) The Advisory Committee may meet as and 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 discharge of its functions shall be such as may be prescribed.

²⁷[**17.-A. Powers 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 provision of this Act or the Rules made thereunder;

(b) production of any document or material object relating to clause (a)

(c) issuing search warrant for any place suspected to the 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 - 28[(1) No person shall open any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, including clinic, laboratory or centre having ultrasound for 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 clinics in duly registered under the Act.]

(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 or exclusively, in counselling or conducting pre-natal diagnostic techniques for any of the purpose mentioned in section 4 immediately before the commencement to 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 counselling or conducting pre-natal diagnostic techniques shall cease to conduct any such counselling or technique on the expiry of six months from the date of commencement of this Act.

27. Inserted by Act 14 of 2003, S. 16 (w.e.f. 14-2-2003).

28. Substituted by Act 14 of 2003, S. 17 for sub-S. (1) (w.e.f. 14-2-2003). Prior to its substitution, sub-S. (1) read as under: -
“(1) No person shall open any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic after the commencement of this Act unless such centre, Laboratory or Genetic Clinic after the commencement of this Act unless such Centre, Laboratory or Clinics is duly registered separately or jointly under this Act.”

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unless such Centre, Laboratory or Clinic has applied for registration and is so registered 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 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 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 motu*, 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 or cancelled for the reasons mentioned in the notice.

(2) If, after giving a reasonable opportunity of being heard to the Genetic Counselling Centre, 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, such period as it may think fit 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 registration of any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic without issuing any such notice referred to in such-section (1).

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

(i) The Central Government, where 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.

**THE PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUE
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CHAPTER VII
OFFENCES AND PENALTIES

²⁹ **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, 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-sections (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 ant notice, circular, label, wrapper or other document including advertisement through internet or any other media in electronic or print form and also includes any visible representation made by means of any hoarding, wall-painting, signal, light, sound, smoke or gas]

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

29. Substituted by Act 14 of 2003, S. 18, for S.22 (w.e.f. 14-2-2003). Prior to its substitution, S.22 read as under: - “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 shall issue or cause to be issued any advertisement in any manner regarding facilities of the pre-natal determination of sex available at such Centre, Laboratory, Clinic or any other place.

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

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

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

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

(3) Any person who seeks the aid 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 of 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 with fine which may extend to one lakh rupees.

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

³¹**[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.]

30. Substituted by Act 14 of 2003, S. 19, for sub-Ss (2) and (3) (w.e.f. 14-2-2003). Prior to their substitution, sub-Ss. (2) and (3) read as under: - “(2) The name of the registered medical practitioner who has been convicted by the Court under sub-section (1), shall be reported by the Appropriate Authority to the respective State Medical Council for taking necessary action including the removal of his name from the register of the Council for a period of two years for the first offence and permanently for the subsequent offence.

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

31. Substituted by Act 14 of 2003, S. 24 (w.e.f. 14-2-2003). Prior to its substitution, S. 24 read as under:- “24. Presumption in the case of conduct of pre-natal diagnostic techniques.-Notwithstanding anything in the Indian Evidence Act, 1872 (1 of 1872), the Court shall presume unless the contrary is proved that the pregnant woman has been compelled by her husband or the relative to undergo pre-natal diagnostic technique and such person shall be liable for abetment of offence under sub-section (3) of section 23 and shall be punishable for the offence specified under that section.”

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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 provided in this Act, shall be punishable with imprisonment for a term which may extend to three months or with fine, which may extend to one thousand rupees or with both and in the case of continuing contravention with an additional fine which may extend to five hundred rupees for every day during which such contravention continues after conviction for the first such contravention.

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

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

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

Explanation- For the purposes 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 non-compoundable – Every offence under this Act shall be cognizable, non-bailable and non-compoundable.

28. Cognizance of offences- (1) No Court shall take cognizance of an offence under this Act except on a complaint made by-

- (a) the Appropriate authority concerned, or any officer authorized in this behalf by the Central Government or State Government, as the case may be, or the Appropriate Authority; or
- (b) a person who has given notice of not less than ³²[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.

32. Substituted by Act 14 of 2003, S. 21, for “thirty days” (w.e.f. 14-2-2003).

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(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, direct the Appropriate Authority to make available copies of the relevant records in its possession to such person.

**CHAPTER VIII
MISCELLANEOUS**

29. Maintenance of records- (1) All records, charts, forms, reports, consent letters and all other documents required to be maintained under this Act and the rules shall be preserved for a 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. – ³³(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 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.]

(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.

33. Substituted by Act 14 of 2003, S.22, for sub-S. (1) (w.e.f. 14-2-2003). Prior to its substitution, sub-S.(1) read as under:- “ (1) if the Appropriate Authority has reason to believe that an offence under this Act has been or is being committed at any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, such Authority or any officer authorized thereof in this behalf may, subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such authority or officer considers necessary, such Genetic Counselling Centre, genetic Laboratory or Genetic Clinic and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize the same if such Authority or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.”

**THE PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUE
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³⁴[**31- A. Removal of difficulties** – (1) If any difficulty arises in giving effect to the provisions of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002, the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of the said Act as appear to it to be necessary or expedient for removing the difficulty:

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

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

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 –

³⁵[(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) the form in which consent of a pregnant woman has to be obtained under section 5;

(iii) the procedure to be followed by the members of the Central Supervisory Board in the discharge of their function under sub-section (4) of section 8;

(iv) allowances for members other than *ex officio* members admissible under sub-section (5) of section 9;

(iva) code of conduct to be observed by persons working at Genetic Counselling Centres, Genetic Laboratories and Genetic 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 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 16-A;

(ivc) empowering the Appropriate Authority in any other matter under clause (d) of section 17-A;]

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

34. Inserted by Act 14 of 2003, S. 23 (w.e.f. 14-2-2003)

35. Substituted by Act 14 of 2003, S.24, for Cl. (i) (w.e.f. 14-2-2003). Prior to its substitution, Cl. (i) read as under :- “(i) the minimum qualifications for persons employed at a registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic under clause (1) of section 3;”

36. Inserted by Act 14 of 2003, s. 24 (w.e.f. 14-2-2003).

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(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 an application shall be made for registration and the fee payable thereof under sub-section (2) of section 18;

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

(ix) the form in which a certificate of registration shall be issued under sub-section (1) of section 19;

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

(xi) the manner in which an appeal may be preferred under section 21;

(xii) the period up to which records, charts, etc., shall be preserved under sub-section (1) of section 29;

(xiii) the manner in which the seizure of documents, records, objects, etc., shall be made and the manner in which seizure list shall be prepared and delivered to the person from whose custody such documents, records or objects were seized under sub-section (1) of section 30;

(xiv) any other matter that is required to be, or may be, prescribed.

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

(a) the time and place of the meetings of the Board and the procedure to be followed for the transaction of business at such meetings and the number of members which shall form the quorum under sub-section (10) of section 9;

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

(c) the method of appointment, the conditions of service and the scales of pay and allowances of the officer and other employees of the Board appointed under section 12;

(d) generally for the efficient conduct of the affairs of the Board.

34. Rules and regulations to be laid before Parliament- Every rule and every regulation made under this Act shall be laid as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation

**THE PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUE
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**THE PRE-CONCEPTION AND PRE-NATAL
DIAGNOSTIC TECHNIQUES (PROHIBITION
OF SEX SELECTION) RULES, 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)², the Central Government hereby makes the following rules, namely:-

1. Short title and commencement:- (1) These rules may be called ³[THE PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION)] RULES, 1996.

(2) They shall come into force on the date⁴ 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) “employees” means a person working in or employed by a Genetic Counselling Centre, a Genetic Laboratory or a Genetic Clinic or an Ultrasound Clinic or Imaging Centre, and includes those working on part-time, contractual, consultancy, honorary or on any other basis;

(c) “Form” means a Form appended to these rules;

⁵[* * *]

(e) “section” means a section of the Act;

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

⁶[(g) “Mobile Medical Unit” means a mobile vehicle which provides specialized facilities for the patients, requiring basic specialist services and provides improved access to healthcare 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.]

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

1. Published in the Gazette of India, Ext., Pt. II, S. 3 (i), dated 1-1-1996.

2. Now *see* the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994

3. Substituted by G.S.R. 109 (E), dated 14-4-2003.

4. 1-1-1996

5. Cl. (d) omitted by G.S.R. 109(E), dated 14-2-2003). Prior to its omission Cl. (d) read as under:- “(d)” “Schedule” means schedule appended to these rules;”

6. Inserted by G.s.r.80 (E), dated 7-2-2012 (w.e.f.9-2-2012)

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(1) Any person being or employing

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

(ii) a medical geneticist,

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

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

(i) A Medical Geneticist and

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

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

(i) Chromosomal studies:

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

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

(3) Inverted microscope.

(4) Incubator and oven.

(5) Carbon dioxide incubator or closed system with 5% CO₂ atmosphere.

(6) Autoclave.

(7) Refrigerator.

(8) Water bath.

(9) Centrifuge.

(10) Vortex mixer.

(11) Magnetic stirrer.

(12) pH Meter.

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

(14) Double distillation apparatus (glass).

(15) Such other equipments as may be necessary.

(ii) Biochemical studies:

(requirements according to tests to be carried out)

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

(2) Inverted microscope.

(3) Incubator and oven.

(4) Carbon dioxide incubator or closed system with 5% CO₂ atmosphere.

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- (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 betacounter) or fluometer for various biochemical tests.
 - (12) Vortex mixer.
 - (13) Magnetic stirrer.
 - (14) pH Meter.
 - (15) A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.
 - (16) Double distillation apparatus (glass).
 - (17) Liquid nitrogen tank.
 - (18) Such other equipments as may be necessary.
- (iii) Molecular studies:
- (1) Inverted microscope.
 - (2) Incubator.
 - (3) Oven.
 - (4) Autoclave.
 - (5) Refrigerators (4 degree and minus 20 degree Centigrade).
 - (6) Water bath.
 - (7) Microcentrifuge.
 - (8) Electrophoresis apparatus and power supply.
 - (9) Vertex Mixer.
 - (10) Magnetic stirrer.
 - (11) pH meter.
 - (12) A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.
 - (13) Double distillation apparatus (glass).
 - (14) P.C.R. machine.
 - (15) Refrigerated centrifuge.
 - (16) U.V Illuminator with photographic attachment or other documentation system.
 - (17) Precision micropipettes.
 - (18) Such other equipments as may be necessary.
- (3)(1) Any person having adequate space and being or employing
- (a) Gynaecologist having experience of performing at least 20 procedures in chorionic vili aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis foetoscopy, foetal skin or organ biopsy or foetal blood sampling, etc., under supervision of an experienced gynaecologist in these fields, or
 - (b) a sonologist, Imaging Specialist, Radiologist or Registered Medical Practitioner having Post Graduate degree or diploma or six months training or one year experience in sonography or image scanning, or

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(c) A medical geneticist,
may set up a genetic clinic/ultrasound clinic/imaging centre.

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

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

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

(c) Appropriate catheters and equipment for carrying out chorionic villus 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 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.]

⁷[(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.]

^{7a}[**3-A. Sale of ultrasound machines/imaging machines-** (1) No organization including a commercial organization or a person, including manufacturer, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment, capable of detecting sex of foetus, shall sell distribute, supply, rent, allow or authorize the use of any such machine or equipment in any manner, whether on payment or otherwise, to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person unless such Centre, Laboratory, Clinic, body or person is registered under the Act.

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

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

7. Inserted by G.S.R. 418(E), dated 4-6-2012 (w.e.f. 5-6-2012).

7a. inserted by G.S.R. 109 (E), dated 14-2-2003 (w.e.f. 14-2-2003).

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⁸[**3-B. Regulation of Portable machines** – (1) The use of portable ultrasound machine or any other 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 conditions, namely

(a) the portable machine being used, within the premises it is registered, for providing services to the indoor patients;

(b) as part of a mobile medical unit, offering a bouquet of other health and medical services.

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

(i) Curative

(a) Referral of complicated cases;

(b) Early detection of TB, Malaria, Leprosy, Kala-Azar and other locally endemic communicable diseases and non-communicable diseases such as hypertension diabetes cataract cases, etc.;

(c) Minor surgical procedures and suturing;

(d) Specialist services such as O and G Specialist, Paediatrician and Physician.

(ii) Reproductive and child Health Services.

(a) Ante natal check up and related services;

(b) Referral or complicated pregnancies;

(c) Promotion of institutional deliveries;

(d) Post-natal check up;

(e) Immunization clinics;

(f) Treatment of common childhood illness;

(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

(a) Investigation facilitates like hemoglobin, urine examination;

(b) Clinical detection of leprosy tuberculosis or endemic diseases;

(c) Screening of cancer, etc.

(v) Specialized facilities and services

(a) X-ray;

(b) ECG;

(c) Ultrasound test.

8. inserted by G.S.R 80(E), dated 7-2-2012 (w.e.f. 9-2-2012)

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(vi) Emergency services and care in times of disaster or epidemic or public health emergency or accident, etc.

(2) Regulations 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 Unit offering a bouquet of other health and medical services, in urban slums or rural or remote or hilly or hard to reach areas for improved access to health care services by underserved populations.

(b) The machine under no circumstances shall be used for sex determination of the foetus.

(c) The stand alone mobile ultrasound clinic offering only pre-natal diagnostic facilities are prohibited.

(d) The mobile medical unit offering diagnostic services shall have adequate space for providing the facilities to patients.]

(4) Registration of ⁹[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres]. – ⁹[(1) An application for registration shall be made to the Appropriate Authority, in duplicate, in Form A duly accompanied by an Affidavit containing –

(i) an undertaking to the effect that the Genetic Centre/Laboratory/Clinic/Ultrasound Clinic/Imaging Centre/Combination thereof, as the case may be, shall not conduct any test or procedure, by whatever name called, for selection of sex before or after conception or for detection of sex of foetus except for diseases specified in section 4(2) nor shall the sex of foetus be disclosed to any body; and

(ii) an undertaking to the effect that the Genetic Centre/Laboratory /Clinic/Combination thereof, as the case may be, shall display prominently a notice that they did 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;]

¹⁰[(iii) the registration of a genetic clinic shall also include the registration of each and every mobile genetic clinic offering pre-natal diagnostic facilities 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.

⁹[**5.Application fee** – (1) Every application for registration under rule 4 shall be accompanied by an application fee of; -

(a) ^{10a}[Rupees twenty five thousand] for Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre.

(b) ^{10a}[Rupees twenty five thousand] for an institute, hospital, nursing home, or any place providing jointly the service of a Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic, Ultrasound Clinics or Imaging Centre or any combination thereof:

9. Substituted by G.S.R. 109(E), dated 14-2-2003 (w.e.f. 14-2-2003)

10. Inserted by G.S.R. 80(E), dated 7-2-2012 (w.e.f.7-2-2012).

10a. Substituted by G.S.R.418 (E), dated 4-6-2012 (w.e.f.5-6-2012).

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Provided that if an application for registration of any Genetic Clinic/Laboratory/Centre, etc., has rejected by the Appropriate Authority, no fee shall be required to be paid on re-submission of the application 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 favor 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 Form B to the applicant. One copy of the certificate of registration shall be displayed by the registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, Ultrasound Clinic or Imaging Centre at a conspicuous place at its place of business:

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

¹¹[(2-A)(a) One copy of the certificate of registration shall be displayed by the registered mobile medical unit inside the vehicle at a conspicuous place.

(b) The certificate of registration for such unit shall clearly specify the following:-

(i) the area of its operation, which shall not exceed the district wherein it is registered;

(ii) the number of portable machines installed and being used in the vehicle;

(iii) the make and model number of the portable machine;

(iv) the registration number of the vehicle;

(v) Full address of the service provider for the mobile medical unit.

(2-B) 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.

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

¹¹ Inserted by G.S.R. 80(E), dated 7-2-2012).

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

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

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

(6) The certificate of registration shall be non-transferable. In the event of change of ownership or change of management or on ceasing to function as a Genetic Counselling Centre of registration shall be surrendered to the Appropriate Authority.

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

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

8. Renewal of Registration: - (1) An application for renewal of certificate of registration shall be made in duplicate in Form A, to the Appropriate Authority thirty days before the date of expiry of the certificate of registration. Acknowledgement of receipt of such application shall be issued by the Appropriate Authority in the manner specified in sub-rule (2) of rule 4.

(2) The Appropriate Authority shall, after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of the Act and these rules and having regard to the advice of the advisory Committee in this behalf, renew the certificate of registration, as specified in form, 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 reason 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 registration shall be one half of the fees provided in sub-rule (1) of rule (5)

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

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(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 –¹²[(1) Every Genetic Counselling Centre, Genetic laboratory, ¹³[Genetic Clinic including a mobile Genetic Clinic], Ultrasound Clinic and Imaging Centre shall maintain a register showing in serial order, the names and addresses of the men or women given genetic counselling, subjected to pre-natal diagnostic procedures or pre-natal diagnostic tests, the names of their spouse or father and the date on which they first reported for such counseling, procedure or test.)

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

¹²[(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.]

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

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

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

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

¹⁴[(8) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre 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.---¹²[(1) Before conducting preimplantation genetic diagnosis, or any pre-natal diagnostic technique/test/procedure such as amniocentesis, chorionic villi biopsy, fetoscopy, foetal skin or organ biopsy or cordocentesis, a written consent, as specified in Form G, in a language the person undergoing such procedure understands, shall be obtained from her/him.]

(1-A) 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 image scanning that he/she has neither detected nor disclosed the sex of foetus of the pregnant woman to anybody. The pregnant women 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

12. Substituted by G.S.R. 109 (E), dated (14-2-2003)

13. Substituted by G.S.R. 80 (E), dated 7-2-2012 (w.e.f.7-2-2012)

14. Inserted by G.S.R. 109 (E), dated 14-2-2003 (w.e.f. 14-2-2003).

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[(11. Facilities for inspection—(1) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre, nursing home, hospital, institute or any other place where any of the machines or equipments capable of performing any procedure, technique or test capable of pre-natal determination of sex or selection of sex before or after conception is used, shall afford all reasonable facilities for inspection of the place, equipment and records of 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 cases of violation of the provisions of the Act in any other manner

(2) The Appropriate Authority or the officer authorized by it may seal and seize any ultrasound machine scanner or any other equipment, capable of detecting sex of foetus, used by any organization if the organization has not got itself registered under the Act. These machines of such organizations shall be confiscated and further action shall be taken as per the provisions of the section 23 of the Act.

12. Procedure for search and seizure.—(1) The Appropriate Authority or any officer authorized in this behalf may enter and search at all reasonable times any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Imaging Centre or Ultrasound Clinic in the presence of two or more independent

“(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 give an undertaking that it shall not undertake detection of sex of foetus or selection of sex before or after conception”.

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

*Explanation.—*In these Rules

- (1) ‘ Genetic Laboratory/Genetic Counselling Centre’ would include an Ultrasound Centre/Imaging Centre/nursing home/hospital/ institute or any other place, by whatever name called, where any of the machine 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 records, machines and equipments; and
- (3) “seize’ and ”seizure” would include “seal” and “sealing” respectively

15. Inserted. by G.S.R. 109(E), dated 14th February, 2003 (w.e.f. 14-2-2003).

16. Substituted by G.S.R. 109(E), dated 14th February, 2003 (w.e.f. 14-2-2003).

17. Substituted by G.S.R. 426(E), dated 31st may, 2011, for sub-rule (2) (w.e.f. 2-6-2011). Sub-rule (2), before substitution, stood as under:

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

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

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

Provided that a copy of the list of such document, record, register, book, pamphlet, advertisement or other material object seized may be delivered under acknowledgement, or sent by registered post to the owner or manager of the (Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre), if no person acknowledging custody of the document, record, register, book, pamphlet, advertisement or other material

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

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

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

13. Intimation of changes in employees, place or equipments.—Every (Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre) shall intimate every change of employee, place, address and equipments installed, to the Appropriate Authority within a period of thirty days of such change.

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 pro-natal diagnostic procedure shall invariably be immediately preceded by locating the foetus and placenta

17a. Substituted by G.S.R. 418(E), dated 4-6-2012 (w.e.f. 5-6-2012).

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

16. Allowances to members of the Central Supervisory Board.—(1) The *ex-officio* members, and other Central and State Government officers appointed to the Board will be entitled to Travelling Allowance and Daily allowance for attending the meetings of the Board as per the Travelling 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 or attending the meetings of the Board as admissible to non-official and members of Parliament as the case may be, under the Travelling Allowances rules of the Central Government.

17. Public Information.—(1) Every (Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre) shall prominently display on its premises a notice in English and in the local language or languages for the information of the public, to 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 (Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre), and shall be made available to the clientele on demand for perusal.

(3) The Appropriate Authority, the Central Government, the State Government, and the Government/Administration of the Union Territory may publish periodically lists of registered (Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre) 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.

¹⁹[**18.** Code of Conduct to be observed by persons working at Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics and Imaging Centres, etc.—All persons including the owners, employee or any other persons associated with Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics and Imaging Centers registered under the Act/ these rules shall

- (i) Not conduct or associate with, or help in carrying out detection or disclosure of sex of foetus in any manner;
- (ii) Not employ or cause to be employed any person not possessing qualifications necessary for carrying out pre-natal diagnostic techniques/ procedures, techniques and tests including ultrasonography;
- (iii) Not conduct or cause to be conducted or aid in conducting by himself or through any other person any techniques or procedure for selection of sex before or after conception or for detection of sex of foetus except for the purposes specified in sub-section (2) of section 4 of the Act;
- (iv) Not conduct or cause to be conducted or aid in conducting by himself or through any other person any techniques or test or procedure under the Act at a place other than a place registered under the Act/these rules;
- (v) Ensure that no provision of the Act and these rules are violated in any manner;
- (vi) Ensure that the person conducting any techniques, test or procedure leading to detection of sex foetus for purposes not covered under section 4(2) of the Act or selection of sex before

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or after conception, is informed that such procedures lead to violation of the Act and these rules which are punishable offences;

- (vii) Help the law enforcing agencies in bring to book the violators of the provisions of the Act and these rules;
- (viii) Display his/her name and designation prominently on the dress worn by him/her;
- (ix) Write his/her name and designation in full under his/her signature;
- (x) On no account conduct or allow/ cause to be conducted female foeticide;
- (xi) Not commit any other act of professional misconduct.

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

(2) Anybody aggrieved by the decision of the Appropriate Authority at district level may appeal to the Appropriate Authority at State/UT level within 30 days of the order of the district level Appropriate Authority.

(3) Each appeal shall be disposed of by the District Appropriate Authority or by the State/Union Territory Appropriate Authority, as the case may be, within 60 days of its receipt.

(4) If an appeal is not made within the time as prescribed under sub-rule (1), (2) or (3), the Appropriate Authority under that sub-rule may condone the delay in case he/she is satisfied that appellant was prevented for sufficient cause from making such appeal.]

SCHEDULE I

²⁰[***]

SCHEDULE II

²⁰[***]

SCHEDULE III

²⁰[***]

²¹[FORM A

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

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

**FORM IF 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 combination of these)
4. Full name and address/addresses of Genetic Counselling Centre/ Genetic Laboratory / Genetic
Clinic/ Ultrasound Clinic/ Imaging Centre with Telephone/Fax number(s)/Telegraphic/Telex/e-
mail address(s).

18. Substituted by G.S.R 109 (E), dated 14-2-2003 (w.e.f. 14-2-2003)

19. Inserted by G.S.R 109 (E), dated 14-2-2003 (w.e.f. 14-2-2003)

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understood the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994)* and the pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1996++.

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

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

(SEAL OF THE ORGANISATION SOUGHT TO BE REGISTERED)

ACKNOWLEDGEMENT

(See rules 4 (2) and 8(1))

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

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

OR

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

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

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

Office of the Appropriate Authority.
(SEAL)

ORIGINAL/ DUPLICATE FOR DISPLAY

FORM B

(See rules 6 (2), 6 (5) and 8 (2))

CERTIFICATE OF REGISTRATION

(To be issued in duplicate)

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

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

Date.....

From.....To.....
Signature, name and designation of
the Appropriate Authority

SEAL

FORM C
(See rule 6(3), 6(5) and 8(3))
FORM FOR REJECTION OF APPLICATION FOR GRANT/RENEWAL OF
REGISTRATION

In exercise of the powers conferred under section 19(2) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 the Appropriate Authority..... hereby rejects the application for grant*/renewal* of registration of the 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*
- (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:

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FORM D

(See rule 9(2))

FORM FOR MAINTENANCE OF RECORDS BY THE GENETIC
COUNSELLING CENTRE

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

Basis of diagnosis:

- (a) Clinical
- (b) Bio-chemical
- (c) Cytogenetic
- (d) Other (eg. radiological, ultrasonography)

10. Indication for pre-natal diagnosis

A. Previous child/children with

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

B. Advanced maternal age (35 years or above)

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

D. Others (specify)

11. Procedure advised*

- (i) Ultrasound
- (ii) Amniocentesis
- (iii) Chorionic villi biopsy
- (iv) Foetoscopy
- (v) Foetal skin organ biopsy
- (vi) Cordocentesis
- (vii) Any other (specify)

12. Laboratory tests to be carried out

- (i) Chromosomal studies
- (ii) Biochemical studies

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- (iii) Molecular studies
- (iv) Preimplantation genetic diagnosis

13. Result of diagnosis

If abdominal give details. Normal/ Abdominal

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

Place:

Date:

FORM E

(See rule 9(3))

FORM FOR MAINTENANCE OF RECORDS BY GENETIC LABORATORY

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. Type of sample: Maternal blood/Chorionic villus sample/amniotic fluid/ Foetal blood or other foetal tissue (specify)
 9. Specify indication for pre-natal diagnosis
- A. Previous child/children with
- (i) Chromosomal disorders
 - (ii) Metabolic disorders
 - (iii) Congenital anomaly
 - (iv) Mental retardation
 - (v) Haemoglobinopathy
 - (vi) Sex linked disorders
 - (vii) Single gene disorder
 - (viii) Any other (specify)

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- (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. Procedures carried out (with name and registration No. of Gyaneacologist/ Radiologist/Registered Medical Practitioner) who performed it.

Non-Invasive

- (i) Ultrasound (specify purpose for which ultrasound is to done during pregnancy
(List of indications for ultrasonography of pregnant women are given in the note below)

Invasive

- (ii) Amniocentesis
- (iii) Chorionic villi biopsy
- (iv) Foetal skin organ biopsy
- (v) Cordocentesis
- (vi) Any other (specify)

12. Any complication of procedure—please specify

13. Laboratory tests recommended*

- (i) Chromosomal studies
- (ii) Biochemical studies
- (iii) Molecular studies
- (iv) Preimplantation genetic diagnosis

14. Result of

- (a) Pre-natal diagnostic procedure
(give details)
- (b) Ultrasonography
(specify abnormality detected, if any). Normal/ Abnormal

15. Date(s)on which procedures carried out.

16. Date on which consent obtained. (In case of invasive)

17. The result of pre-natal diagnostic procedure were conveyed to.....on.....

18. Was MTP advised/conducted?

19. Date on which MTP carried put.

Date:

Name, Signature and Registration number of the

Place:

Gynaecologist/ Radiologist/ Director of the Clinic

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DECLARATION OF PREGNANT WOMAN

I, Ms.....(name of the pregnant woman) declare that by undergoing ultrasonography/ image scanning, etc. I do not want to know the sex of my foetus.

Signature/ thumb impression of pregnant woman

**DECLARATION OF DOCTOR/ PERSON CONDUCTING ULTRASONOGRAPHY/
IMAGE SCANNING**

I.....(name of the person conducting ultrasonography/ image scanning) declare that while conducting ultrasonography/ image scanning on Ms..... (name of the pregnant woman), I have neither detected no disclosed the sex of her foetus to anybody in any manner.

Name and signature of the person conducting ultrasonography/image scanning/Director or owner of genetic clinic/ultrasound clinic/Imaging centre

Important Note:

- (i) Ultrasound is not indicated/ advised/ performed to determine the sex of foetus except for diagnosis of sex-linked diseases such as Duchenne Muscular Dystrophy, Haemophilia A&B, etc.
- (ii) During pregnancy Ultrasonography should only be performed when indicated. The following is the representative list of indications for ultrasound during pregnancy
 - (1) To diagnose intra-uterine and/or ectopic pregnancy and confirm viability.
 - (2) Estimation of gestational age(dating).
 - (3) Detection of number of foetuses and their chorionicity.
 - (4) Suspected pregnancy with IUCD in-situ or suspected pregnancy following contraceptive failure/MTP failure.
 - (5) Vaginal bleeding/leaking.
 - (6) Follow-up of cases of abortion.
 - (7) Assessment of cervical canal and diameter of internal os.
 - (8) Discrepancy between uterine size and period of amenorrhoea.
 - (9) Any suspected adnexal or uterine pathology/ abnormality.
 - (10) Detection of chromosomal abnormalities, foetal structural defects and other abnormalities and other abnormalities and their follow-up.
 - (11) To evaluate foetal presentation and position.
 - (12) Assessment of liquor amnii
 - (13) Preterm labour/ preterm premature rupture of membranes.
 - (14) Evaluation of placental position, thickness, grading and abnormalities
(placenta praevia, retroplacental position, thickness, grading and abnormalities
(placenta praevia, retroplacental haemorrhage, abnormal adherence, etc.
 - (15) Evaluation of umbilical cord-presentation, insertion, nuchal encirclement,
number of vessels and presence of true knot.
 - (16) Evaluation of previous Caesarean Section scars.
 - (17) Evaluation of foetal growth parameters, foetal weight and foetal well being.
 - (18) Colour flow mapping and duplex Doppler studies.
 - (19) Ultrasound guided procedures such as medical termination of pregnancy,
external, cephalic version, etc., and their follow-up.
 - (20) Adjunct to diagnostic and therapeutic invasive interventions such as chorionic

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villus sampling (CVS), amniocenteses, foetal blood sampling, foetal skin biopsy, amnio infusion, intrauterine infusion, intrauterine infusion, placement of shunts, etc.

- (21) Observation of intra-partum events.
- (22) Medical/ surgical conditions complicating pregnancy.
- (23) Research/ scientific studies in recognized institutions.

Person conducting ultrasonography on a pregnant woman shall keep complete record thereof in the clinic/centre in Form-F and any deficiency or inaccuracy found therein shall amount to contravention of provisions of section 5 or section 6 of the Act, unless contrary is proved by the person conducting such ultrasonography.

FORM G
(See rule 10)
FORM OF CONSENT
(For invasive techniques)

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

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

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

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

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

Date: _____ Signature of the pregnant woman.

Place:

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

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

Date

Name, Address and Registration number of Genetic Clinic/ Institute
SEAL

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FORM H

(See rule 9(5))

FORM FOR MAINTENANCE OF PERMANENT RECORD OF APPLICATIONS FOR GRANT/
REJECTION OF REGISTRATION UNDER THE PRE-NATAL DIAGNOSTIC TECHNIQUES
(REGULATION AND PREVENTION OF MISUSE ACT, 1994

1. Sl.No.
2. File number of Appropriate Authority
3. Date of receipt of application for grant of registration.
4. Name, Address, Phone/ Fax, etc., of Applicant:
5. Name and address(es) of Genetic Counselling Centre*/ Genetic Laboratory*/ Genetic Clinic*/ Ultrasound Clinic*/ Imaging Centre*
6. Date of consideration by advisory Committee and recommendation of Advisory Committee, in summary.
7. Outcome of application (stage granted/ rejected and state of issue orders-record date of issue of order in Form B or 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 Center will be allotted in the event of change of ownership or management.
- (d) Registration number shall not be allotted twice
- (e) Each Genetic Counselling Centre/ Genetic Laboratory/ Genetic Clinic/ Ultrasound Clinic/ Imaging Center may be allotted a folio consisting of two pages of the Register for recording Form H
- (f) The space provided for “additional information” may be used for recording suspension, cancellation, rejection of applications for renewal, change of ownership/ management, outcome of any legal proceedings, etc.
- (g) Every folio (i.e.2 pages) of the Register shall be authenticated by signature of the Appropriate Authority with date, and every subsequent entry shall also be similarly authenticated.]