

**The
Pre-conception and
Pre-natal Diagnostic
Techniques (Prohibition
of Sex Selection)
Act, 1994**

(57 of 1994)

as amended by

The Jammu and Kashmir Reorganisation Act, 2019

(34 of 2019) (w.e.f. 31-10-2019)

with

- **The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996**
- **The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014**

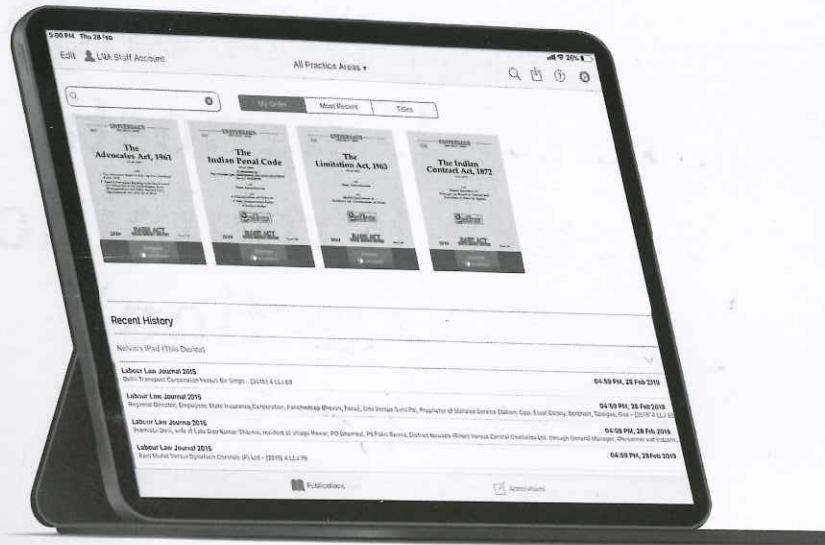
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- **The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014**

along with
SHORT NOTES

Universal





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

INTRODUCTION

In the recent past Pre-natal Diagnostic Centres sprang up in the urban areas of the country using pre-natal diagnostic techniques for determination of sex of the foetus. Such centres became very popular and their growth was tremendous as the female child is not welcomed with open arms in most of the Indian families. The result was that such centres became centres of female foeticide. Such abuse of the technique is against the female sex and affects the dignity and status of women. Various Organisations working for the welfare and uplift of the women raised their heads against such an abuse. It was considered necessary to bring out a legislation to regulate the use of, and to provide deterrent punishment to stop the misuse of, such techniques. The matter was discussed in Parliament and the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Bill, 1991 was introduced in the Lok Sabha. The Lok Sabha after discussions adopted a motion for reference of the said Bill to a Joint Committee of both the Houses of Parliament in September, 1991. The Joint Committee presented its report in December, 1992 and on the basis of the recommendations of the Committee, the Bill was reintroduced in the Parliament.

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. A legislation is required to regulate the use of such techniques and to provide deterrent punishment to stop such inhuman act.

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) permitting the use of such techniques only under certain conditions by the registered institutions; and
- (v) punishment for violation of the provisions of the proposed legislation.

ACT 57 OF 1994

The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Bill having been passed by both the Houses of Parliament received the assent of the President on 20th September, 1994. It came on the Statute Book as the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994). By section 3 of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002 (14 of 2003) the nomenclature of the Act has been amended and now it stands as THE PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION) ACT, 1994 (57 of 1994) (Came into force on 1-1-1996).

LIST OF AMENDING ACTS

1. The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2001 (32 of 2001) (w.e.f. 3-9-2001).
2. The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002 (14 of 2003) (w.e.f. 14-2-2003).
3. The Jammu and Kashmir Reorganisation Act, 2019 (34 of 2019) (w.e.f. 31-10-2019).

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 purposes of detecting genetic abnormalities or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex-linked disorders and for the prevention of their misuse for sex determination leading to female foeticide and for matters connected therewith or incidental thereto.]

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

CHAPTER I PRELIMINARY

1. Short title, extent and commencement.—(1) This Act may be called ²[the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection)] Act, 1994.

(2) It shall extend to the whole of India ³[***].

(3) It shall come into force on such date⁴ 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;

⁵[(ba) “conceptus” means any product of conception at any stage of development from fertilisation until birth including extra embryonic membranes as well as the embryo or foetus;

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

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

1. Subs. by Act 14 of 2003, sec. 2, for the long title (w.e.f. 14-2-2003).

2. Subs. by Act 14 of 2003, sec. 3, for “the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse)” (w.e.f. 14-2-2003).

3. The words “except the State of Jammu and Kashmir” omitted by the Jammu and Kashmir Reorganisation Act, 2019 (34 of 2019), secs. 95, 96 and Fifth Sch., Table-1 (w.e.f. 31-10-2019).

4. Came into force on 1-1-1996, vide S.O. 990(E), dated 20th December, 1995, published in the Gazette of India, Extra., Pt. II, Sec. 3 (ii), dated 21st December, 1995.

- (c) "Genetic Counselling Centre" means an institute, hospital, nursing home or any place, by whatever name called, which provides for genetic counselling to patients;
- (d) "Genetic Clinic" means a clinic, institute, hospital, nursing home or any place, by whatever name called, which is used for conducting pre-natal diagnostic procedures;

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

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

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

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

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

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

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

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

- ³(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 tests;

1. Ins. by Act 4 of 2003, sec. 4 (w.e.f. 14-2-2003).

2. Subs. by Act 14 of 2003, sec. 4, for clause (g) (w.e.f. 14-2-2003).

3. Subs. by Act 14 of 2003, sec. 4, for clause (i) (w.e.f. 14-2-2003).

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

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

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

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

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

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

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

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

CHAPTER II

REGULATION OF GENETIC COUNSELLING CENTRES, GENETIC LABORATORIES AND GENETIC CLINICS

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

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

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

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

1. Subs. by Act 14 of 2003, sec. 4, for clause (k) (w.e.f. 14-2-2003).

2. Ins. by Act 14 of 2003, sec. 4 (w.e.f. 14-2-2003).

COMMENTS

Genetic Counselling Centers, Genetics Laboratories, Genetic Clinics, unless registered under the Act, can conduct or associate with, or help in, conducting activities relating to pre-natal diagnostic techniques. They cannot employ or cause to be employed or take services of any person whether on honorary basis or on payment who does not possess the prescribed qualifications. Medical geneticist, gynaecologist, pediatrician, registered medical practitioner or any other person cannot conduct or cause to be conducted or aid in conducting by himself or through any other person, any pre-natal diagnostic techniques at a place other than a registered place.

¹[3A. **Prohibition of sex-selection.**—No person, including a specialist or a team of specialists in the field of infertility, shall conduct or cause to be conducted or aid in conducting by himself or by any other person, sex selection on a woman or a man or on both or on any tissue, embryo, conceptus, fluid or gametes derived from either or both of them.

COMMENTS

Sex selection on a woman or a man or on both or on any tissue, embryo, conceptus, fluid or gametes destined from either or both of them is prohibited.

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

COMMENTS

Sale of any ultrasound machine or imaging machine or scanner or any other equipment capable of detecting sex of foetus to any Genetic Counselling Center, Genetic Laboratory, Genetic Clinic or any other person not registered under the Act is prohibited.

CHAPTER III

REGULATION OF PRE-NATAL DIAGNOSTIC TECHNIQUES

4. 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 except 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 except for the purposes of detection of any of the following abnormalities, namely:—
 - (i) chromosomal abnormalities;
 - (ii) genetic metabolic diseases;
 - (iii) haemoglobinopathies;
 - (iv) sex-linked genetic diseases;
 - (v) congenital anomalies;
 - (vi) any other abnormalities or diseases as may be specified by the Central Supervisory Board*;

1. Ins. by Act 14 of 2003, sec. 6 (w.e.f. 14-2-2003).

* Supervisory Board has specified as follows:—

"any other indication of possible genetic disease/anomaly in the foetus such as sporadic genetic disease in the couple, a positive screening test for carrier status or positive result of

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

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

Provided that the person conducting ultrasonography on a pregnant woman shall keep complete record thereof in the clinic in such manner, as may be prescribed, and any deficiency or inaccuracy found therein shall amount to contravention of the provisions of section 5 or section 6 unless contrary is proved by the person conducting such ultrasonography;

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

(5) no person including a relative or husband of a woman shall seek or encourage the conduct of any sex-selection technique on her or him or both.]

COMMENTS

There is no substance in the submission that provision of Section 4(3) be read down. The proviso to Section 4(3) reflects the importance of records in such cases, as they are often the only source to ensure that an establishment is not engaged in sex determination. Non-maintenance of record is spring board for commission of offence of foeticide, not just a clerical error; *Federation of Obstetrics and Gynecological Societies of India (FOGSI) v. Union of India and Ors.* [Writ Petition (Civil) No. 129 of 2017, decided on 3rd May, 2019], LNIND 2019 SC 392.

5. Written consent of pregnant woman and prohibition of communicating the sex of foetus.—(1) No person referred to in clause (2) of section 3 shall conduct the pre-natal diagnostic procedures unless—

- (a) he has explained all known side and after effects of such procedures to the pregnant woman concerned;
- (b) he has obtained in the prescribed form her written consent to undergo such procedures in the language which she understands; and
- (c) a copy of her written consent obtained under clause (b) is given to the pregnant woman.

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

1 Subs. by Act 14 of 2003, sec. 7, for clause (3) and (4) of section 3 of the Act.

COMMENTS

Pre-natal diagnostic procedures cannot be conducted unless (i) all side and after effects of such procedures have been explained to the concerned pregnant woman, (ii) her written consent to undergo such procedures has been obtained in the language which she understands, and (iii) a copy of her written consent is given to the concerned pregnant woman. Communication of sex of the foetus by words, signs or in any other manner to the concerned pregnant woman or her relations or any other person is prohibited.

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 in its Centre, Laboratory or Clinic, pre-natal diagnostic techniques including ultrasonography, for the purpose of determining the sex of a foetus;
- (b) no person shall conduct or cause to be conducted any pre-natal diagnostic techniques including ultrasonography for the purpose of determining the sex of a foetus.
- ¹[(c) no person shall, by whatever means, cause or allow to be caused selection of sex before or after conception.]

COMMENTS

No Genetic Counselling Centres or Genetic Laboratories or Genetic Clinic or any person can conduct or cause to be conducted pre-natal diagnostic techniques including ultrasonography for the purpose of determining the sex of a foetus. No person can cause or allow to be, caused selection of sex before or after conception.

CHAPTER IV

CENTRAL SUPERVISORY 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*;
- ²[(c) three members to be appointed by the Central Government to represent the Ministries of Central Government in charge of Women and Child Development, Department of Legal Affairs or Legislative Department in the Ministry of Law and Justice, and Indian System of Medicine and Homoeopathy, *ex officio*];
- (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;
- ³[(ii) eminent gynaecologist and obstetrician or expert of *stri-roga* or *prasuti-tantra*.;]

- (iii) eminent paediatricians;
- (iv) eminent social scientists; and
- (v) representatives of women welfare 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 years; ¹[***]

²[Provided that the term of office of a member elected under clause (f) of sub-section (2) of section 7 shall come to an end as soon as the member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the House of the People, or the Deputy Chairman of the Council of States or ceases to be a member of the House from which he was elected; and]

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

(2) If a casual vacancy occurs in the office of any other members, whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, such vacancy shall be filled by the Central Government by making a fresh appointment and the member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

(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 business at its meetings (including the quorum at such meetings) as may be provided by regulations:

Provided that the Board shall meet at least once in six months.

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

(3) If for any reason the Chairman or the Vice-Chairman is unable to attend any meeting of the Board, any other member chosen by the members present at the meeting shall preside at the meeting.

(4) All questions which come up before any meeting of the Board shall be decided by a majority of the votes of the members present and voting, and in the event of an equality of votes, the Chairman, or in his absence, the person presiding, shall have and exercise a second or casting vote.

(5) Members other than *ex officio* members shall receive such allowances, if any, from the Board as may be prescribed.

10. Vacancies, etc., not to invalidate proceedings of the Board.—No act or proceeding of the Board shall be invalid merely by reason of—

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

11. Temporary association of persons with the Board for particular purposes.—(1) The Board may associate with itself, in such manner and for such purposes as may be determined by regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

(2) A person associated with it by the Board under sub-section (1) for any purpose shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the Board and shall not be a member for any other purpose.

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

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

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

13. Authentication of orders and other instruments of the Board.—All 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. Disqualifications for appointment as member.—A person shall be disqualified for being appointed as a member if, he—

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

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

²[Provided that no member other than an *ex officio* member shall be appointed for more than two consecutive terms.]

³**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 techniques, sex selection techniques 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 Centres, Genetic Laboratories and Genetic Clinics;
- (v) to oversee the performance of various bodies constituted under the Act and taken appropriate steps to ensure its proper and effective implementation;
- (vi) any other functions as may be prescribed under the Act.]

⁴**16A. Constitution of State Supervisory Board and Union territory Supervisory Board.**—(1) Each State and Union territory having Legislature shall constitute a Board to be known as the State Supervisory Board or the Union territory Supervisory Board, as the case may be, which shall have the following functions:—

1. Subs. Act 14 of 2003, sec. 11, for clause (f) (w.e.f. 14-2-2003).
 2. Ins. by Act 14 of 2003, sec. 12 (w.e.f. 14-2-2003).
 3. Subs. by Act 14 of 2003, sec. 13, for section 16 (w.e.f. 14-2-2003).

- (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 prescribed in respect of the various activities undertaken in the State under the Act to the Board and the Central Government; and
 - (v) any other functions as may be prescribed under the Act.
- (2) The State Board shall consist of,—
- (a) the Minister in charge of Health and Family Welfare in the State, who shall be the Chairperson, *ex officio*;
 - (b) Secretary in charge of the Department of Health and Family Welfare who shall be the Vice-Chairperson, *ex officio*;
 - (c) Secretaries or Commissioners in charge of Departments of Women and Child Development, Social Welfare, Law and Indian System of Medicines and Homoeopathy, *ex officio*, or their representatives;
 - (d) Director of Health and Family Welfare or Indian System of Medicines and Homoeopathy of the State Government, *ex officio*;
 - (e) three women members of Legislative Assembly or Legislative Council;
 - (f) ten members to be appointed by the State Government out of which two each shall be from the following categories:—
 - (i) eminent social scientists and legal experts;
 - (ii) eminent women activists from non-governmental organisations or otherwise;
 - (iii) eminent gynaecologists and obstetricians or experts of *stri-roga* or *prasuti-tantra*;
 - (iv) eminent paediatricians or medical geneticists;
 - (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 a member, other than an *ex officio* member, shall be three years.
- (5) If a vacancy occurs in the office of any member other than an *ex officio* member, it shall be filled by making fresh appointment.
- (6) If a member of the Legislative Assembly or member of the Legislative Council who is a member of the State Board, becomes Minister or Speaker or Deputy Speaker of the Legislative Assembly or Chairperson or Deputy Chairperson of the Legislative Council, he shall cease to be a member of the

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

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

(9) The co-opted members shall have the same powers and functions as other members, except the right to vote and shall abide by the rules and regulations.

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

CHAPTER V

APPROPRIATE AUTHORITY AND ADVISORY COMMITTEE

17. Appropriate Authority and Advisory Committee.—(1) The Central Government shall appoint, by notification in the Official Gazette, one or more Appropriate Authorities for each of the Union territories for the purposes 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 purposes of this Act having regard to the intensity of the problem of pre-natal sex determination leading to female foeticide.

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

¹[(a) when appointed for the whole of the State or the Union territory, consisting of the following three members:—

- (i) an officer of or above the rank of the Joint Director of Health and Family Welfare—Chairperson;
- (ii) an eminent woman representing women's organisation; and
- (iii) an officer of Law Department of the State or the Union territory concerned:

Provided that it shall be the duty of the State or the Union territory concerned to constitute multi-member State or Union territory level Appropriate Authority within three months of the coming into force of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002:

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

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

- (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;
 - (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;
 - ¹(e) to take appropriate legal action against the use of any sex selection technique by any person at any place, *suo motu* or brought to its notice and also to initiate independent investigations in such matter;
 - (f) to create public awareness against the practice of sex selection or pre-natal determination of sex;
 - (g) to supervise the implementation of the provisions of the Act and rules;
 - (h) to recommend to the Board and State Boards modifications required in the rules in accordance with changes in technology or social conditions;
 - (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 functions, and shall appoint one of the members of the Advisory Committee to be its Chairman.

(6) The Advisory Committee shall consist of—

- (a) three medical experts from amongst gynaecologists, obstetricians, paediatricians and medical geneticists;
- (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.

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

(8) The Advisory Committee may meet as 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:

1. Ins. by Act 14 of 2003, sec. 15 (w.e.f. 14-2-2003).

2. Subs. by Act 14 of 2003, sec. 15, for sub-section (7) (w.e.f. 14-2-2003)

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

(9) The terms and conditions subject to which a person may be appointed to the Advisory Committee and the procedure to be followed by such Committee in the discharge of its functions shall be such as may be prescribed.

[17A. 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 provisions 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 be indulging in sex selection techniques or pre-natal sex determination; and
- (d) any other matter which may be prescribed.]

CHAPTER VI

REGISTRATION OF GENETIC COUNSELLING CENTRES, GENETIC LABORATORIES AND GENETIC CLINICS

18. Registration of Genetic Counselling Centres, Genetic Laboratories or Genetic Clinics.—²[(1) No person shall open any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, including clinic, laboratory or centre having ultrasound or imaging machine or scanner or any other technology capable of undertaking determination of sex of foetus and sex selection, or render services to any of them, after the commencement of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002 unless such Centre, Laboratory or Clinic is duly registered under the Act.]

(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 purposes mentioned in section 4, immediately before the commencement of this Act, shall apply for registration within sixty days from the date of such commencement.

(4) Subject to the provisions of section 6, every Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic engaged in 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 unless such Centre, Laboratory or Clinic has applied for registration and is so registered separately or jointly or till such application is disposed of, whichever is earlier.

1. Ins. by Act 14 of 2003, sec. 16 (w.e.f. 14-2-2003).

(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.

COMMENTS

No Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, including clinic, laboratory or centre having ultrasound or imaging machine or scanner or any other technology capable of undertaking determination of sex of foetus and sex selection can be opened unless it is duly registered under the Act.

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

(2) If, after the inquiry and after giving an opportunity of being heard to the applicant and having regard to the advice of the Advisory Committee, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of this Act or the rules, it shall, for reasons to be recorded in writing, reject the application for registration.

(3) Every certificate of registration shall be renewed in such manner and after such period and on payment of such fees as may be prescribed.

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

20. Cancellation or suspension of registration.—(1) The Appropriate Authority may *suo moto*, or on complaint, issue a notice to the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic to show cause why its registration should not be suspended 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, suspend its registration for 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 the public interest, it may, for reasons to be recorded in writing, suspend the registration of any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic without issuing any such notice referred to in sub-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.

CHAPTER VII

OFFENCES AND PENALTIES

¹22. Prohibition of advertisement relating to pre-conception and pre-natal determination of sex and punishment for contravention.—(1) No person, organisation, 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 organisation including Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement in any manner regarding pre-natal determination or pre-conception selection of sex by any means whatsoever, scientific or otherwise.

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

Explanation.—For the purposes of this section, “advertisement” includes any notice, circular, label, wrapper or any other document including advertisement through internet or any other media in electronic or print form and also includes any visible representation made by means of any hoarding, wall-painting, signal, light, sound, smoke or gas.]

COMMENTS

Advertisement relating to pre-conception and pre-natal determination of a sex or sex selection is prohibited. Contravention is punishable with imprisonment upto three years and with fine upto ten thousand rupees.

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 a term which may extend to three years and with fine which may extend to ten thousand rupees and on any

subsequent conviction, with imprisonment which may extend to five years and with fine which may extend to fifty thousand rupees.

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

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

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

COMMENTS

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 therein and renders his professional or technical services there, whether on an honorary basis or other wise and who contravenes any of the provisions of the Act or rules made thereunder shall be punishable with imprisonment upto three years and with fine upto ten thousand rupees and on any subsequent conviction, with imprisonment upto five years and with fine upto fifty thousand rupees. The name of the registered medical practitioner shall be reported to the State Medical Council concerned for taking necessary action. If any person seeks aid for sex selection or for conducting pre-natal diagnostic techniques or any pregnant woman, he shall be punishable with imprisonment upto three years and with fine upto fifty thousand rupees for the first offence and for any subsequent offence, with imprisonment upto five years and with fine upto one lakh rupees.

²[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.]

25. Penalty for contravention of the provisions of the Act or rules for which no specific punishment is provided.—Whoever contravenes any of the provisions of this Act or any rules made thereunder, for which no penalty has

1. Subs. by Act 14 of 2003, sec. 19, for sub-sections (2) and (3) (w.e.f. 14-2-2003).

2. Subs. by Act 14 of 2003, sec. 19, for sub-section (2) (w.e.f. 14-2-2003).

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

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

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

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

Explanation.—For the 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 authorised in this behalf by the Central Government or State Government, as the case may be, or the Appropriate Authority; or
- (b) a person who has given notice of not less than ¹[fifteen days] in the manner prescribed, to the Appropriate Authority, of the alleged offence and of his intention to make a complaint to the court.

Explanation.—For the purpose of this clause, "person" includes a social organisation.

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

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

CHAPTER VIII
MISCELLANEOUS

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

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

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

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

(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 authorised 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.

²[**31A. Removal of difficulties.**—(1) If any difficulty arises in giving effect to the provisions of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002, the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of the said Act as appear to it to be necessary or expedient for removing the difficulty:

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

(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—

- ¹[(i) the minimum qualifications for persons employed at a registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic under clause (2) of section 3;
- (ia) the manner in which the person conducting ultrasonography on a pregnant woman shall keep record thereof in the clinic under the proviso to sub-section (3) of section 4;
- (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 functions under sub-section (4) of section 8;
- (iv) allowances for members other than *ex officio* members admissible under sub-section (5) of section 9;
- ²[(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 16A;
- (ivc) empowering the Appropriate Authority in any other matter under clause (d) of section 17A;]
- (v) the period intervening between any two meetings of the Advisory Committee under the proviso to sub-section (8) of section 17;
- (vi) the terms and conditions subject to which a person may be appointed to the Advisory Committee and the procedure to be followed by such Committee under sub-section (9) of section 17;
- (vii) the form and manner in which 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;

1. Subs. by Act 14 of 2003, sec. 22, for sub-section (1) (w.e.f. 14-2-2003).

2. Ins. by Act 14 of 2003, sec. 23 (w.e.f. 14-2-2003).

1. Subs. by Act 14 of 2003, sec. 24, for clause (i) (w.e.f. 14-2-2003).

- (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 (1) of section 9;
- (b) the manner in which a person may be temporarily associated with the Board under sub-section (1) of section 11;
- (c) the method of appointment, the conditions of service and the scales of pay and allowances of the officer and other employees of the Board appointed under section 12;
- (d) generally for the efficient conduct of the affairs of the Board.

34. Rules and regulations to be laid before Parliament.—Every rule and every regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation.

THE PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION) RULES, 1996¹

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

1. Short title and commencement.—²[(1) These rules may be called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996.]

(2) They shall come into force on the date³ of their publication in the Official Gazette.

2. Definitions.—In these rules, unless the context otherwise requires,—

- (a) "Act" means The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994)[†];
- (b) "employee" means a person working in or employed by a ²[Genetic Counselling Centre, a Genetic Laboratory or a Genetic Clinic, or an Ultrasound Clinic and 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;
- ⁴["***"]
- (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.
- ⁵[(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.]
- ⁵[(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.]

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

(1) Any person being or employing—

- (i) a gynaecologist or a paediatrician having six months experience or four weeks training in genetic 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 centre and get it registered as a genetic counselling centre.

1. *Vide* G.S.R. 1(E), dated 1st January, 1996, published in the Gazette of India, Extra., Pt. II, Sec. 3 (i), dated 1st January, 1996.

† Now the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994).

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

3. Came into force on 1-1-1996.

4. Clause (d) omitted by G.S.R. 109(E), dated 14th February, 2003 (w.e.f. 14-2-2003).

5. Ins. by G.S.R. 80(E), dated 7th February, 2012 (w.e.f. 9-2-2012).

- (2) (a) Any person having adequate space and being or employing—
- (i) a Medical Geneticist and
 - (ii) a laboratory technician, having a B.Sc. degree in Biological Sciences or a degree or diploma in medical laboratory course with at least one year experience in conducting appropriate prenatal diagnostic techniques, tests or procedures.
may set up a genetic laboratory.
- (b) Such laboratory should have or acquire such of the following equipments as may be necessary for carrying out chromosomal studies, bio-chemical studies and molecular studies:—
- (i) *Chromosomal studies:*
- (1) Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.
 - (2) Photo-microscope with fluorescent source of light.
 - (3) Inverted microscope.
 - (4) Incubator and oven.
 - (5) Carbon dioxide incubator or closed system with 5% 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.
 - (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 Radioimmunoassay system (with gamma beta-counter) or fluorometer for various biochemical tests.
 - (12) Vortex mixer.
 - (13) Magnetic stirrer.
 - (14) pH meter.
 - (15) A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.
 - (16) Double distillation apparatus (glass).
 - (17) Liquid nitrogen tank.
 - (18) Such other equipments as may be necessary.

(iii) *Molecular studies:*

- (1) Inverted microscope.
 - (2) Incubator.
 - (3) Oven.
 - (4) Autoclave.
 - (5) Refrigerators (4 degree and minus 20 degree Centigrade).
 - (6) Water bath.
 - (7) Microcentrifuge.
 - (8) Electrophoresis apparatus and power supply.
 - (9) Vertex mixer.
 - (10) Magnetic stirrer.
 - (11) pH meter.
 - (12) A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.
 - (13) Double distillation apparatus (glass).
 - (14) P.C.R. machine.
 - (15) Refrigerated centrifuge.
 - (16) U.V. Illuminator with photographic attachment or other documentation system.
 - (17) Precision micropipettes.
 - (18) Such other equipments as may be necessary.
- (3) (1) Any person having adequate space and being or employing—
- (a) Gynaecologist having experience of performing at least 20 procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis foetoscopy, foetal skin or organ biopsy or foetal blood sampling etc., under supervision of an experienced gynaecologist in these fields, or
 - ¹(b) a Sonologist or imaging specialist or registered medical practitioner having Post Graduate degree or diploma or six months training duly imparted in the manner prescribed in the "the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014; or]
 - (c) A medical geneticist,
- may set up a genetic clinic/ultrasound clinic/imaging centre.
- (2) The Genetic Clinic/ultrasound clinic/imaging centre should have or acquire such of the following equipments, as may be necessary for carrying out the tests or procedures—
- (a) equipment and accessories necessary for carrying out clinical examination by an obstetrician or gynaecologist;
 - (b) an ultra-sonography machine including mobile ultrasound machine, imaging machine or any other equipment capable of conducting foetal ultrasonography;
 - (c) appropriate catheters and equipment for carrying out chorionic villi aspirations per vagina or per abdomen;
 - (d) appropriate sterile needles for amniocentesis or cordocentesis;
 - (e) a suitable foetoscope with appropriate accessories for foetoscopy, foetal skin or organ biopsy or foetal blood sampling shall be optional.
 - (f) equipment for dry and wet sterilization;
 - (g) equipment for carrying out emergency procedures such as evacuation of uterus or resuscitation in case of need;
 - (h) genetic works station.]

1. Subs. by G.S.R., 13(E), dated 9th January, 2014, for sub-clause (b) (w.e.f. 10-1-2014). Sub-clause (b), before substitution, stood as under:

"(b) a Sonologist, Imaging Specialist, Radiologist or Registered Medical Practitioner having

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

²[3A. Sale of ultrasound machines/imaging machines.—(1) No organization including a commercial organization or a person, including manufacturer, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment, capable of detecting sex of foetus, shall sell, distribute, supply, rent, allow or authorize the use of any such machine or equipment in any manner, whether on payment or otherwise, to any Genetic Counselling Centre, Genetic Laboratory, Genetic 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.]

³[3B. Regulation of portable machines.—(1) The use of portable ultrasound machine or any other portable machine or device which has the potential for selection of sex before conception or detection of sex during pregnancy shall be permitted only in the following conditions, namely:—

- (a) the portable machine being used, within the premises it is registered, for providing services to the indoor patients;
- (b) 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 for complicated pregnancies;
- (c) Promotion of institutional deliveries;

- (d) Post-natal check up;
- (e) Immunization clinics;
- (f) Treatment of common childhood illness;
- (g) Treatment of Reproductive Tract Infection or Sexually Transmitted Infections;
- (h) Adolescents care such as lifestyle education, counselling, treatment of minor ailments.

(iii) Family Planning Services

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

(iv) Diagnostic

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

(v) Specialised facilities and services

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

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

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

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

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

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

²[(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 authorised in this behalf, shall acknowledge receipt of the application for registration, in the

acknowledgement slip provided at the bottom of Form A, immediately if delivered at the office of the Appropriate Authority, or not later than the next working day if received by post.

¹[5. **Application Fee.**—(1) Every application for registration under rule 4 shall be accompanied by an application fee of—

- (a) ²[rupees twenty-five thousand] for Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre.
- (b) ³[rupees thirty-five thousand] for an institute, hospital, nursing home, or any place providing jointly the service of a Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic, Ultrasound Clinic or Imaging Centre or any combination thereof:

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

⁴[Provided further that no government institution which provides health and medical services shall be required to pay fee for registration and renewal of registration.]

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

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

(2) Having regard to the advice of the Advisory Committee the Appropriate Authority shall grant a certificate of registration, in duplicate, in Form B to the applicant. One copy of the certificate of registration shall be displayed by the registered ¹[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre] at a conspicuous place at its place of business:

Provided that the Appropriate Authority may grant a certificate of registration to a Genetic Laboratory or a Genetic Clinic 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.

⁴[(2A) (a) One copy of the certificate of registration shall be displayed by the registered mobile medical unit inside the vehicle at a conspicuous place.

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

- (I) the area of its operation, which shall not exceed the district wherein it is registered;
- (II) the number of portable machines installed and being used in the vehicle;

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

2. Subs. by G.S.R. 418(E), dated 4th June, 2012, for "Rs. 3000.00" (w.e.f. 5-6-2012).

3. Subs. by G.S.R. 418(E), dated 4th June, 2012, for "Rs. 4000.00" (w.e.f. 5-6-2012).

4. Ins. by G.S.R. 599(E), dated 19th June, 2017 (w.e.f. 19-6-2017).

5. Ins. by G.S.R. 80(E), dated 7th February, 2012 (w.e.f. 9-2-2012).

- (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.]

¹[(2B) The portable equipment used for conducting pre-natal diagnostic test shall be an integral part of the mobile medical unit and such equipment shall not be used outside such unit under any circumstances.]

¹[(2C) In case of a breakdown of the vehicle or for any other reason due to which the registered unit cannot be used as a Genetic Clinic, the Appropriate Authority has to be informed within a period of seven days.]

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

(4) An enquiry under sub-rule (1), including inspection at the premises of the ²[Genetic Counselling Centre, Genetic Laboratory Genetic Clinic, Ultrasound Clinic or Imaging Centre], shall, be carried out only after due notice is given to the applicant by the Appropriate Authority.

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

(6) The certificate of registration shall be non-transferable. In the event of change of ownership or change of management or on ceasing to function as a ²[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre], both copies of the certificate of registration shall be surrendered to the Appropriate Authority.

(7) In the event of change of ownership or change of management of the ²[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre], the new owner or manager of such Centre, Laboratory or Clinic shall apply afresh for grant of certificate of registration.

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

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

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

1. Ins. by G.S.R. 80(E), dated 7th February, 2012 (w.e.f. 9-2-2012).

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

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

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

(5) On receipt of the renewed certificate of registration in duplicate or on receipt of communication of rejection of application for renewal, both copies of the earlier certificate of registration shall be surrendered immediately to the Appropriate Authority by the ¹[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic Ultrasound Clinic or Imaging Centre].

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

9. Maintenance and preservation of records.—¹[(1) Every Genetic Counselling Centre, Genetic Laboratory, ²[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 counselling, 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.

¹[(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.]

¹[(4) The record to be maintained by every ²[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 applications for grant or renewal of certificate of registration as specified in Form H. Letters of intimation of every change of employee, place, address and equipment installed shall also be preserved a 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 ¹[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

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

2. Subs. by G.S.R. 80(E), dated 7th February, 2012 for "Genetic Clinic" (w.e.f. 02-02-2012)

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 ¹[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.

²[(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.—¹[(1) Before conducting preimplantation genetic diagnosis, or any pre-natal diagnostic technique/test/procedure such as amniocentesis, chorionic villi biopsy, foetoscopy, foetal skin or organ biopsy or cordocentesis, a written consent, as specified in Form G, in a language the person undergoing such procedure understands, shall be obtained from her/him:]

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

²[(1A) Any person conducting ultrasonography/image scanning on a pregnant woman shall give a declaration on each report on ultrasonography/image scanning that he/she has neither detected nor disclosed the sex of foetus of the pregnant woman to any body. The pregnant woman shall before undergoing ultrasonography/image scanning declare that she does not want to know the sex of her foetus.]

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

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

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

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

detection/disclosure of sex of foetus or for detection of cases of violation of the provisions of the Act in any other manner.

¹[(2) The Appropriate Authority or the officer authorised by it may seal and seize any ultrasound machine, scanner or any other equipment, capable of detecting sex of foetus, used by any organisation if the organisation has not got itself registered under the Act. These machines of such organisations 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.—²[(1) The Appropriate Authority or any officer authorised in this behalf may enter and search at all reasonable times any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Imaging Centre or Ultrasound Clinic in the presence of two or more independent witnesses for the purposes of search and examination of any record, register, document, book, pamphlet, advertisement, or any other material object found therein and seal and seize the same if there is reason to believe that it may furnish evidence of commission of an offence punishable under the Act.

Explanation.—In these Rules—

- (1) 'Genetic Laboratory/Genetic Clinic/Genetic Counselling Centre' would include an Ultrasound Centre/Imaging Centre/nursing home/hospital/institute or any other place, by whatever name called, where any of the machines or equipments capable of selection of sex before or after conception or performing any procedure technique or test for 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.]

(2) A list of any document, record, register, book, pamphlet, advertisement or any other material object found in the ²[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 authorised in this behalf and by the witnesses to the seizure:

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

1. Subs. 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:

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

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

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

Provided that a copy of the list of such document, record, register, book, pamphlet, advertisement or other material object seized may be delivered under acknowledgement, or sent by registered post to the owner or manager of the ¹[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 object seized is available at the place of effecting the seizure.

(4) If any material object seized is perishable in nature, the Appropriate Authority, or the officer authorised 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 ¹[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre] for preserving such perishable material object may be sealed until such time as arrangements can be made for safe removal of such perishable material object and in such eventuality, mention of keeping the material object seized, on the premises of the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall be made in the list of seizure.

(5) In the case of non-completion of search and seizure operation, the Appropriate Authority or the officer authorized in this behalf may make arrangements, by way of mounting a guard or sealing of the premises of the ¹[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 equipment.—Every ¹[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre] shall intimate every change of employee, place, address and equipment installed, to the Appropriate Authority ²[at least thirty days in advance of the expected date of such change, and seek re-issuance of certificate of registration from the Appropriate Authority, with the changes duly incorporated.]

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

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

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

2. Subs. by G.S.R. 418(E), dated 4th June, 2012, for "within a period of thirty days of such change" (w.e.f. 5-6-2012).

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 ¹[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 ¹[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 ¹[Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics and Imaging Centres] and findings from the reports and other information in their possession, for the information of the public and for use by the experts in the field.

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

- (i) not conduct or associate with, or help in carrying out detection or disclosure of sex of foetus in any manner;
- (ii) not employ or cause to be employed any person not possessing qualifications necessary for carrying out pre-natal diagnostic techniques/procedures, techniques and tests including ultrasonography;

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

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

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

¹[**18A. Code of Conduct to be observed by Appropriate Authorities.**—(1) All the Appropriate Authority including the State, District and Sub-district notified under the Act, *inter-alia*, shall observe the following general code of conduct, namely:—

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

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

- (i) ensure that the re-constitution, functions and other relevant matters related to advisory committee shall be in accordance with the provisions of the Advisory Committee Rules, 1996;

1. Ins. by G.S.R. 119(E), dated 24th February, 2014 (w.e.f. 26-2-2014).

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

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

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

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

- (i) dispose of the application for renewal and new registration within a period of seventy days from the date of receipt of application;
- ¹[(ii) ensure that no application for fresh registration or renewal of registration is accepted if any case is pending in any court against the applicant for violation of any provision of the Act and the rules made thereunder.]

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

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

1. Subs. by G.S.R. 60(E), dated 28th January, 2015, for clause (ii) (w.e.f. 28-1-2015). Clause (ii), before substitution, stood as under:

“(ii) ensure that no application for fresh registration or renewal is accepted if any case is pending in any court against the applicant.”

- (iv) suspend the certificate of registration in the course of taking legal action of seizure, and sealing of the facility;
- (v) ensure that there shall be no violation of the provisions of the Medical Termination of Pregnancy Act, 1971 (34 of 1971) and the Rules made thereunder while implementing the provisions of the Pre-conception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996;
- (vi) take immediate action for filing appeal, revision or other proceeding in higher courts in case of order of acquittal within a period of thirty days but not later than fifteen days of receipt of the order of acquittal.

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

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

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

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

- (i) conduct regular inspection of all the registered facilities once in every ninety days and shall preserve the inspection report as documentary evidence and a copy of the same be handed over to the owner of facility inspected and obtain acknowledgement in respect of the inspection;
- (ii) place all the inspection reports once in three months before the Advisory Committee for follow up action;

- (iii) maintain bimonthly progress report containing number of cases filed and persons convicted, registration made, suspended or cancelled, medical licenses cancelled, suspended, inspections conducted, Advisory Committee meetings held at the district level and quarterly progress report at the State level;
- (iv) (a) procure the copy of the charges framed within seven days and in the case of doctors, the details of the charges framed shall be submitted within seven days of the receipt of copy of charges framed to the State Medical Council;
- (b) procure the certified copy of the order of conviction as soon as possible and in the case of conviction of the doctors, the certified copy of the order of conviction shall be submitted within seven days of the receipt of copy of the order of conviction.

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

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

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

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

[19. Appeals.—(1) Anybody aggrieved by the decision of the Appropriate Authority at 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.]

[19A. The manner for filing and disposal of the appeal under clause (i) and (ii) of section 21 of the Act.—(1)(a) The Central Government may, by notification in the Official Gazette, appoint a Central Appellate Authority for each of the Union territories, for the purpose of hearing appeal against the order of the Central Appropriate Authority or the Union territory Appropriate Authority.

(b) The Central Appellate Authority shall consist of an officer not below the rank of the Union territory Appropriate Authority.

(2)(a) The State Government may, by notification in the Official Gazette, appoint a State Appellate Authority for the whole State, for the purpose of appeal against the order of State Appropriate Authority.

(b) The State Appellate Authority shall consist of the Principal Secretary, Health and Family Welfare or an officer not below the rank of the State Appropriate Authority as notified by the State Government.

(3)(a) An appeal against the order of suspension or cancellation of registration passed by the Central Appropriate Authority or the Union territory Appropriate Authority shall lie with the Central Appellate Authority.

(b) An appeal against the order of suspension or cancellation of registration passed by the State Appropriate Authority shall lie with the State Appellate Authority appointed by the State Government.

(4) An appeal to the Central Appellate Authority or the State Appellate Authority shall—

- (a) be made in the form of a memorandum of appeal specified in Form I;
- (b) be accompanied by an Affidavit explaining the facts of the case, specified in form J; and
- (c) contain an index, synopsis and list of documents as specified in Appendix A.

(5) Every appeal before the Central Appellate Authority or the State Appellate Authority shall be supported by the following documents, namely:—

- (a) self certified copies of orders or documents against which appeal is being preferred;

- (b) copies of documents relied upon by the appellant;
- (c) index to the appeal; and
- (d) synopsis containing particulars of events and list of documents.

(6) Every appeal shall be filed within a period of thirty days of the date of receipt of the order against which the appeal is preferred:

Provided that the Central Appellate Authority or the State Appellate Authority may allow the appeal after the period of thirty days, if there is a sufficient cause for not filing the appeal within the said period.

(7) The Central Appellate Authority or the State Appellate Authority shall issue notice to the respondent, which shall be served in any of the following modes, namely:—

- (a) service by the appellant; or
- (b) by hand delivery (dasti); or
- (c) by registered post with acknowledgement due; or
- (d) by electronic mail or fax.

(8)(a) The Central or the State Appellate Authority shall hear the parties on receipt of the appeal and shall intimate the date of hearing which shall be seven days before the date of hearing, by email or courier at the address mentioned in the appeal.

(b) The appellant may present in person or through his duly authorised legal representative, at the time of hearing of the appeal.

(c) If the appellant fails to appear before the Central Appellate Authority or the State Appellate Authority on the specific date, the appeal may be dismissed for default:

(d) The Central Appellate Authority or the State Appellate Authority may, if sufficient cause is shown, at any stage of appeal, grant time to the parties or to any of them and may from time to time adjourn the hearing of the appeal for reasons to be recorded in writing.

Provided that more than three adjournments shall not be given to the appellant.

(e) The Appeal shall be disposed of within a period of sixty days from the date of filing of the appeal.

(9) The Central Appellate Authority or the State Appellate Authority shall dispose of the appeal by passing a speaking order in writing and issue under the seal of the Central Appellate Authority or the State Appellate Authority duly authenticated by the officer authorised by the Central Appellate Authority or the State Appellate Authority for this purpose within a period of sixty days from the date of receipt of the appeal.]

¹[***]

²[FORM A

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

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

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

1. Name of the applicant
(Indicate name of the organisation sought to be registered)
2. Address of the applicant
3. Type of facility to be registered
(Please specify whether the application is for registration of a Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre or any combination of these)
4. Full name and address/addresses of Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre with Telephone/Fax number(s)/Telegraphic/Telex/E-mail address(s).
5. Type of ownership of Organisation (individual ownership/partnership/company/co-operative/any other to be specified). In case type of organization is other than individual ownership, furnish copy of articles of association and names and addresses of other persons responsible for management, as enclosure.
6. Type of Institution (Govt. Hospital/Municipal Hospital/Public Hospital/Private Hospital /Private Nursing Home/Private Clinic/Private Laboratory/any other to be stated.
7. Specific pre-natal diagnostic procedures/tests for which approval is sought
 - (a) Invasive Amniocentesis/Chorionic villi aspiration/
Chromosomal/Biochemical/Molecular studies
 - (b) Non-Invasive Ultrasonography
Leave blank if registration is sought for Genetic Counselling Centre only.
8. Equipment available with the make and model of each equipment (List to be attached on a separate sheet).
9. (a) Facilities available in the Counselling Centre.
(b) Whether facilities are or would be available in the Laboratory/Clinic for the following tests:—
 - (i) Ultrasound
 - (ii) Amniocentesis
 - (iii) Chorionic villi aspiration
 - (iv) Foetoscopy
 - (v) Foetal biopsy
 - (vi) Cordocentesis

1. Schedule I, Schedule II and Schedule III omitted by G.S.R. 109(E), dated 14th February, 2003 (w.e.f. 14-2-2003).

- (c) Whether facilities are available in the Laboratory/Clinic for the following:—
- Chromosomal studies
 - Biochemical studies
 - Molecular studies
 - Preimplantation genetic diagnosis

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

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

DECLARATRION

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

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

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

[SEAL OF THE ORGANISATION SOUGHT TO BE REGISTERED]

ACKNOWLEDGEMENT
[See rules 4 (2) and 8 (1)]

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

† Now the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection)
Act, 1994 (57 of 1994).

†† Now the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection)

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

OR

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

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

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

SEAL]

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

ORIGINAL/DUPLICATE FOR DISPLAY

[FORM B

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

CERTIFICATE OF REGISTRATION

(To be issued in duplicate)

- 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.....
- This registration is granted subject to the aforesaid Act and rules framed
thereunder and any contravention thereof shall result in suspension or cancellation
of this Certificate of Registration before the expiry of the said period of five years
apart from prosecution.
 - Name and address of the Genetic Counselling Centre*/Genetic
Laboratory*/Genetic Clinic*/Ultrasound Clinic*/Imaging Centre*.
 - Pre-natal diagnostic procedures* approved for (Genetic Clinic). Non-Invasive
 - Ultrasound Invasive
 - Amniocentesis
 - Chorionic villi biopsy
 - Foetoscopy
 - Foetal skin or organ biopsy
 - Cordocentesis
 - Any other (specify)

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

† Now the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection)
Act, 1994 (57 of 1994).

- 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) From.....to.....
- Date..... Signature, name and designation of
the Appropriate Authority

SEAL]

* Strike out whichever is not applicable or necessary

DISPLAY ONE COPY OF THIS CERTIFICATE AT A CONSPICUOUS PLACE AT THE PLACE OF BUSINESS

[FORM C

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

FORM FOR REJECTION OF APPLICATION FOR GRANT/RENEWAL OF REGISTRATION

In exercise of the powers conferred under section 19 (2) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994)[†], the Appropriate Authorityhereby rejects the application for grant*/renewal* of registration of the undermentioned Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*/Ultrasound Clinic*/Imaging Centre*.

- (1) Name and address of the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*/Ultrasound Clinic*/Imaging Centre*
- (2) Reasons for rejection of application for grant/renewal of registration:

Date..... Signature, name and designation of
Place..... the Appropriate Authority with
SEAL]

* Strike out whichever is not applicable or necessary.

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

† Now the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994).

[FORM D

[See rule 9 (2)]

FORM FOR MAINTENANCE OF RECORDS BY THE GENETIC COUNSELLING CENTRE

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

- (iii) Chorionic villi biopsy
 - (iv) Foetoscopy
 - (v) Foetal skin or organ biopsy
 - (vi) Cordocentesis
 - (vii) Any other (specify)
12. Laboratory tests to be carried out
- (i) Chromosomal studies
 - (ii) Biochemical studies
 - (iii) Molecular studies
 - (iv) Preimplantation genetic diagnosis
13. Result of diagnosis If abnormal give details. Normal/Abnormal
14. Was MTP advised?
15. Name and address of Genetic Clinic to which patient is referred.
16. Dates of commencement and completion of genetic counselling.

Place..... Name, Signature and Registration No. of the
Date..... Medical Geneticist/Gynaecologist/Paediatrician
administering Genetic Counselling]

*Strike out whichever is not applicable or necessary.

[FORM E

[See rule 9 (3)]

FORM FOR MAINTENANCE OF RECORDS BY GENETIC LABORATORY

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

- (ii) Metabolic disorders
- (iii) Malformation(s)
- (iv) Mental retardation
- (v) Hereditary haemolytic anaemia
- (vi) Sex linked disorder
- (vii) Single gene disorder
- (viii) Any other (specify)

B. Advanced maternal age
(35 years or above)

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

D. Other (specify)

10. Laboratory tests carried out (give details)

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

11. Result of diagnosis

If abnormal give details.

Normal/Abnormal

12. Date(s) on which tests carried out.

The results of the Pre-natal diagnostic tests were conveyed to.....
on.....

Place.....
Date.....

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

Strike out whichever is not applicable or necessary.

[FORM F

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

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

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

1. Name and complete address of Genetic Clinic/Ultrasound Clinic/Imaging centre:.....
2. Registration No. (Under PC & PNDT Act, 1994)
3. Patient's name.....Age.....
4. Total Number of living children:

- (a) Number of living Sons with age of each living son (in years or months):
.....
- (b) Number of living Daughters with age of each living daughter (in years or months):
.....
5. Husband's/Wife's/Father's/Mother's Name:
6. Full postal address of the patient with Contact Number, if any.....
.....
7. (a) Referred by (Full name and address of Doctor(s)/Genetic Counseling Centre):
.....
.....
(Referral slips to be preserved carefully with Form F)
- (b) Self-Referral by Gynaecologist/Radiologist/Registered Medical Practitioner conducting the diagnostic procedures:
- (Referral note with indications and case papers of the patient to be preserved with Form F)
- Self-referral does not mean a client coming to a clinic and requesting for the test or the relative/s requesting for the test of a pregnant woman**
8. Last menstrual period or weeks of pregnancy:

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

9. Name of the doctor performing the procedure/s:
10. Indication/s for diagnosis procedure..... (specify with reference to the request made in the referral slip or in a self-referral note)
- (Ultrasonography prenatal diagnosis during pregnancy should only be performed when indicated. The following is the representative list of indications for ultrasound during pregnancy. (Put a "Tick" against the appropriate indication/s for ultrasound)
- (i) To diagnose intra-uterine and/or ectopic pregnancy and confirm viability.
- (ii) Estimation of gestational age (dating).
- (iii) Detection of number of fetuses and their chorionicity.
- (iv) Suspected pregnancy with IUCD in-situ or suspected pregnancy following contraceptive failure/MTP failure.
- (v) Vaginal bleeding/leaking.
- (vi) Follow-up of cases of abortion.
- (vii) Assessment of cervical canal and diameter of internal os.
- (viii) Discrepancy between uterine size and period of amenorrhoea.
- (ix) Any suspected adnexal or uterine pathology/abnormality.
- (x) Detection of chromosomal abnormalities, fetal structural defects and other abnormalities and their follow-up.
- (xi) To evaluate fetal presentation and position.
- (xii) Assessment of liquor amnii.
- (xiii) Preterm labor/preterm premature rupture of membranes.
- (xiv) Evaluation of placental position, thickness, grading and abnormalities (placenta praevia, retro-placental haemorrhage, abnormal adherence etc.).

- (xv) Evaluation of umbilical cord - presentation, insertion, nuchal encirclement, number of vessels and presence of true knot.
- (xvi) Evaluation of previous Caesarean Section scars.
- (xvii) Evaluation of fetal growth parameters, fetal weight and fetal well being.
- (xviii) Color flow mapping and duplex Doppler studies.
- (xix) Ultrasound guided procedures such as medical termination of pregnancy, external cephalic version etc. and their follow-up.
- (xx) Adjunct to diagnostic and therapeutic invasive interventions such as chorionic villus sampling (CVS), amniocenteses, fetal blood sampling, fetal skin biopsy, amnio-infusion, intrauterine infusion, placement of shunts etc.
- (xxi) Observation of intra-partum events.
- (xxii) Medical/surgical conditions complicating pregnancy.
- (xxiii) Research/scientific studies in recognized institutions.
11. Procedures carried out (Non-Invasive) (Put a "Tick" on the appropriate procedure)
- (i) Ultrasound
- (Important Note: Ultrasound is not indicated/advised/performed to determine the sex of fetus except for diagnosis of sex-linked diseases such as Duchene Muscular Dystrophy, Haemophilia A & B etc.)**
- (ii) Any other (specify)
12. Date on which declaration of pregnant woman/person was obtained:
13. Date on which procedures carried out:
14. Result of the non-invasive procedure carried out (report in brief of the test including ultrasound carried out)
15. The result of pre-natal diagnostic procedures was conveyed to.....
on.....
16. Any indication for MTP as per the abnormality detected in the diagnostic procedures/tests.....
.....

Date.....

Name, Signature and Registration Number with Seal of the

Place.....

Gynaecologist/Radiologist/Registered Medical
Practitioner performing Diagnostic Procedure/s

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

17. Name of the doctor/s performing the procedure/s:
18. History of genetic/medical disease in the family (specify):
- Basis of diagnosis ("Tick" on appropriate basis of diagnosis):
- (a) Clinical (b) Bio-chemical
- (c) Cytogenetic (d) other (e.g. radiological, ultrasonography etc.-specify)
19. Indication/s for the diagnosis procedure ("Tick" on appropriate indication/s):
- A. Previous child/children with:
- (i) Chromosomal disorders (ii) Metabolic disorders
- (iii) Congenital anomaly (iv) Mental Disability

- (v) Haemoglobinopathy (vi) Sex linked disorders
- (vii) Single gene disorder (viii) Any other (specify)
- B. Advanced maternal age (35 years)
- C. Mother/father/sibling has genetic disease (specify)
- D. Other (specify).....
- 20. Date on which consent of pregnant woman/person was obtained in Form G prescribed in PC&PNDT Act, 1994:
- 21. Invasive procedures carried out ("Tick" on appropriate indication/s)
 - i. Amniocentesis ii. Chorionic Villi aspiration
 - iii. Fetal biopsy iv. Cordocentesis
 - v. Any other (specify)
- 22. Any complication/s of invasive procedure (specify)
- 23. Additional tests recommended (Please mention if applicable)
 - (i) Chromosomal studies (ii) Biochemical studies
 - (iii) Molecular studies (iv) Pre-implantation gender diagnosis
 - (v) Any other (specify)
- 24. Result of the Procedures/Tests carried out (*report in brief of the invasive tests/procedures carried out*)
- 25. Date on which procedures carried out:
- 26. The result of pre-natal diagnostic procedures was conveyed to..... on.....
- 27. Any indication for MTP as per the abnormality detected in the diagnostic procedures/tests.....

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

SECTION D: Declaration

DECLARATION OF THE PERSON UNDERGOING PRENATAL DIAGNOSTIC TEST/PROCEDURE

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

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

In Case of thumb Impression:

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

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

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

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

Signature:

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

FORM G

[See rule 10]

FORM OF CONSENT

(For invasive techniques)

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

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

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

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

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

Date.....
Place.....

Signature of the pregnant woman.

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

Name, Address and Registration number of Genetic Clinic/Institute

Date.....

SEAL]

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

* Now the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994)

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 (state granted/rejected and date of issue of orders-record date of issue of order in Form B or Form C)
8. Registration number allotted and date of expiry of registration
9. Renewals (date of renewal and renewed upto)
10. File number in which renewals dealt
11. Additional information, if any

Name, Designation and Signature of
Appropriate Authority

Guidance for Appropriate Authority

- (a) Form H is a permanent record to be maintained as a register, in the custody of the Appropriate Authority.
- (b) *Means strike out whichever is not applicable.
- (c) On renewal, the Registration Number of the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre will not change. A fresh registration Number will be allotted in the event of change of ownership or management.

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

† Now the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994).

- (d) Registration number shall not be allotted twice.
- (e) Each Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/ Ultrasound Clinic/Imaging Centre may be allotted a folio consisting of two pages of the Register for recording Form H.
- (f) The space provided for 'additional information' may be used for recording suspension, cancellations, rejection of application for renewal, change of ownership/management, outcome of any legal proceedings, etc.
- (g) Every folio (*i.e.*, 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.]

FORM I

[See rule 19A(4)(a)]

**BEFORE THE CENTRAL APPELLATE AUTHORITY OR
THE STATE APPELLATE AUTHORITY**

Appeal No. /20.....

In the matter of:

Name and Address of Appellant

Appellant

Versus

Name and Address of the Authority

Whose order is challenged

Respondent

Most respectfully showeth:

The above mentioned appellant appeals against the order passed by the....., concerned Appropriate Authority at (Name of place and address) against the appellant in (details of the case if any) dated and sets forth the following grounds of objection of the order appealed:—

1. Particulars of the order including number of order, if any, against which the appeal is preferred
2. Brief facts of the case
3. Findings of the Appropriate Authority challenged
4. Grounds of appeal
5. Copy of the order enclosed along with all the documents relied upon by the Appellant
6. Any other information/documents in support of appeal
7. Prayer

That the appellant, therefore prays for the reasons stated above and as may be argued at the time of hearing, the records and proceedings be called for, this appeal be allowed, the order under the appeal be set aside and quashed, and order deemed just and proper may kindly be passed in favour of the appellant.

Signature of the Appellant

Place.....

Date.....

1. Ins. by G.S.R. 492(E), dated 22nd May, 2017 (w.e.f. 23-5-2017).

Verification

I, do hereby verify that the contents of para to are true and correct to the best of my knowledge and belief and no part is false and nothing material has been concealed therein.

Signature of the Appellant]

[FORM J

[See rule 19A(4)(b)]

PROFORMA AFFIDAVIT

BEFORE THE CENTRAL APPELLATE AUTHORITY or THE STATE APPELLATE AUTHORITY

In the matter of:

Name of the Appellant

Appellant

Versus

Concerned Appropriate Authority

Respondent

Affidavit

IS/o-D/oagedR/odo hereby solemnly declare as under:

- 1. That I am the Appellant in the captioned matter filed before the Appellate Authority and aware of all the facts and circumstances of the case, hence competent to swear this affidavit.
2. That the accompanying Memo of Appeal has been drafted by my counsel under my instruction and the same has been understood by me, the same may be read as the part and parcel of this affidavit, and the same has not been repeated here for the sake of brevity.

Deponent

Verification

Verified on this day of (month and year) that the contents of the appeal are true and correct on the basis of my knowledge/records/ documents/legal advice received from the counsel and nothing material has been concealed therefrom.

Deponent]

[APPENDIX A

[See rule 19A(4)(c)]

BEFORE THE CENTRAL APPELLATE AUTHORITY or THE STATE APPELLATE AUTHORITY

In the matter of:

Name of the Appellant

Appellant

Versus

Concerned Appropriate Authority

Respondent

Index

Table with 3 columns: Sl. No., Particulars, Page No.

Signature of the Appellant

Synopsis

Table with 2 columns: Date, Particulars of events

Signature of the Appellant

LIST OF DOCUMENTS

Table with 3 columns: Sl. No., Particulars, Pages

Signature of the Appellant]

THE PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION) (SIX MONTHS TRAINING) RULES, 2014¹

In exercise of the powers conferred by clause (i) of sub-section (2) of section 32 of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994), the Central Government hereby makes the following rules, namely:—

1. Short title and commencement.—(1) These rules may be called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014.

(2) They shall come into force on the date² of their publication in the Official Gazette.

2. Definitions.—In these rules, unless the context otherwise requires,—

- (a) "Act" means the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994);
- (b) "principal rules" means the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996;
- (c) "six months training" means the training imparted under these rules.
- (d) "syllabus" means the syllabus given in Schedule I;
- (e) "Log book and assessment" means the Log book and assessment as specified in Schedule II;
- (f) words and expressions used herein and not defined in these rules but defined in the Act or in the principal rules, as the case may be, shall have the meanings, respectively, assigned to them in the Act or in the principle rules.

3. Nomenclature of the six months training in ultrasonography.—The six months training imparted under these rules shall be known as "the Fundamentals in Abdomino-Pelvic Ultra sonography: Level one for M.B.B.S. Doctors".

4. Period of the training.—The period of training for obtaining a certificate of training shall be 300 clock hours.

5. Components of the six months training curriculum.—(1) The major components of the training curriculum shall be—

- (a) theory based knowledge to equip registered medical practitioners with the knowledge, professional skills, attitudes and clinical competencies;
- (b) skill-based knowledge;
- (c) log book and assessment.

1. Vide G.S.R. 14(E), dated 9th January, 2014, published in the Gazette of India, Pt. II, Sec. 3(i), No. 11, dated 10th January, 2014.

2. Came into force on 10-1-2014.

(2) The comprehensive syllabus for the said six months training is as specified in Schedule I.

(3) The details related to log book and assessment are as specified in Schedule II.

6. Eligibility for training.—(1) Any registered medical practitioner shall be eligible for undertaking the said six months training.

(2) The existing registered medical practitioners, who are conducting ultrasound procedures in a Genetic Clinic or Ultrasound Clinic or Imaging Centre on the basis of one year experience or six months training are exempted from undertaking the said training provided they are able to qualify the competency based assessment specified in Schedule II and in case of failure to clear the said competency based exam, they shall be required to undertake the complete six months training, as provided under these rules, for the purpose of renewal of registrations.

7. Accreditation of institutions for six months training and its recognition.—

(1) The following teaching institutions would be accredited as training centres to impart the six months training, namely:—

- (a) Centres of Excellence established under the Acts of Parliament;
- (b) Medical Council of India recognised institutions offering Post Graduate programmes in Obstetrics or Gynaecology and Radiology;
- (c) Institutions offering full-time residency DNB programme in Obstetrics or Gynaecology and Radiology.

(2) The names of the institutions recognised for this purpose shall be notified State-wise by the State Health Medical Education Department:

Provided that the training institutes recognised for imparting the six months training shall maintain the standards of infrastructure, equipment and manpower including the faculty as per apex regulatory bodies like the Medical Council of India or the National Board of Examination.

8. Selection of students.—(1) The selection and intake of registered medical practitioners for admission to such trainings shall be on the basis of the following criteria:

- (a) Intake for admission to such trainings shall be in 1:1 student to teacher ratio and training to be incurred in the Department of Radiology.
- (b) Selection shall be as per the merit list of the State Post-graduate entrance exam.
- (c) 20% reservation for *in service* candidates.

9. Changed criteria to be made prospective.—These rules shall come into force with immediate effect in case of new registrations. However, all registered medical practitioners employed in a Genetic Clinic or Ultrasound Clinic or Imaging Centre on the basis of one year experience or six months training and failed to qualify the competency based exam as specified in Schedule II shall have to apply and clear six months training on or before 1st January, 2017.

10. Fee structure for the training.—(1) The training fee for conducting the six months training shall not exceed Rs. 20,000.

(2) For registered medical practitioners who are already registered for conducting ultra sonography in a Genetic Clinic or Ultrasound Clinic or Imaging Centre and require to clear a competency based evaluation, the fee shall not exceed Rs. 10,000.

(3) Fee structure or waiver thereof for *in service* registered medical practitioners shall be decided by the respective State Governments.

11. Staff-Faculty.—(1) The institute conducting the said six months training for registered medical practitioners shall appoint the Post-graduate teachers in Radiology or Obstetrics or Gynaecology recognised by the respective regulatory bodies as full time faculty for the said training programme.

(2) The Deans or Head of the respective teaching institutions shall be responsible for monitoring the training programme in entirety.

12. Monitoring requirements.—Monitoring of the training institutions imparting the six months training shall be as per the existing norms laid down by the respective apex regulatory bodies.

13. Competency based evaluation.—The final competency-based evaluation at the end of the six months training shall be held as per the mechanism specified in Schedule II.

14. Validity of the training certificate.—Certification of training obtained from any State shall be applicable for the purposes of registration under Act in all States.

SCHEDULE I

FUNDAMENTALS IN ABDOMINO PELVIC ULTRASONOGRAPHY: Level one 6 Months Course for M.B.B.S. Doctors

Ultrasonography Syllabus

This training will equip individuals with the knowledge, professional skills, attitudes and clinical competencies to use ultrasound imaging in an appropriate and safe manner.

Training will have broadly two components:

1. Knowledge Based

The theoretical course – will cover lectures on Physics of ultrasound, ultrasound machines & probes, How to use ultrasound, Pre-natal Diagnostic Techniques Act, laws of ultrasound, Medicolegal aspects, Methodology, patient preparations, Complete Obstetric Ultrasound uses including use in first, second & third trimesters, Diagnosis of threatened abortion, ectopic pregnancy, biometry, anomaly scanning, Intra-Uterine Growth Retardation (IUGR), Placental evaluation, Amniotic fluid evaluation, color doppler uses and 3D & 4D ultrasound. Complete Gynecological uses in evaluating female pelvis and evaluating infertility.

2. Skill Based

- (1) Ability to visualise in two dimensional image and a three dimensional structure.
- (2) Hand-Eye co-ordination.
- (3) Supervision is essential.

Summary Listing

I. Knowledge based: Theory Course

The contents of the theoretical course should include at least the following, in addition to covering the subjects outlined in the syllabus above:

(A) Principles of Ultrasound Examination

- (i) Physics, instrumentation and safety
- (ii) Ultrasound systems and probes
- (iii) Instrumentation and control panel

(B) Conduct of ultrasound scanning

- (i) Consent
- (ii) Chaperone
- (iii) Confidentiality
- (iv) Infection control
- (v) Examination technique: probe movements and image orientation

(C) Normal pelvic anatomy

- (i) The Ultrasound Scan appearances of the normal uterus, ovary, endometrium and pelvis
- (ii) Endometrial and ovarian changes during menstrual cycles
- (iii) How to take measurements of dimensions of pelvic structures
- (iv) Measurement of endometrial thickness

(D) Early pregnancy

- (i) The Ultrasound Scan appearances in early pregnancy - Embryo, Placenta, Gestational Age, Twin pregnancy
- (ii) Recognition and diagnosis of complications of early pregnancy including
 - (a) extra-uterine pregnancy
 - (b) miscarriage
 - (c) retained products of conception.

(E) Identification or Recognition of pelvic pathology

- (i) Use of Ultrasound Scan in managing menorrhagia, inter menstrual bleeding, post menopausal bleeding
- (ii) Ultrasound Scan appearances in polycystic ovaries, uterine fibroids, adenomyosis and endometrial polyps
- (iii) Ultrasound Scan appearances of ovarian cysts-corporis luteum, simple and complex cysts and masses
- (iv) Complex ovarian masses or ovarian screening
 - (a) Endometrial pathology in post-menopausal women
 - (b) Gestational trophoblastic neoplasia
 - (c) Chronic pelvic pain
 - (d) The assessment of tubal patency in infertility and follicular tracking for assisted conception
 - (e) The assessment of prolapse, incontinence, and anal sphincter damage

(F) Reproductive medicine

- (i) Effect of contraceptive hormones and menopause on the endometrium
- (ii) Use of Ultrasound Scan in identification of Intra-uterine Device or Intra-uterine System and Implanon position

Note.—Attendance at a theoretical course is mandatory. The theoretical course need not include any hands-on component

II. Skills Based**(A) Basic Imaging Skills**

- (i) Machine set-up
- (ii) Counselling for scan
- (iii) Decide transabdominalvs. transvaginal route
- (iv) Choice of probe
- (v) Patient positioning
- (vi) Orientation
- (vii) Identify normal endometrium
- (viii) Identify normal myometrium
- (ix) Identify normal ovaries
- (x) Measure cervical length
- (xi) Recording images
- (xii) Note keeping and documentation

(B) Early Pregnancy

- (i) Confirm viability
- (ii) Date pregnancy
- (iii) Diagnose corpus luteum cyst
- (iv) Diagnose multiple pregnancy
- (v) Determine chorionicity/zygosity
- (vi) Identify retroplacental haematoma
- (vii) Diagnose anembryonic pregnancy
- (viii) Diagnose missed miscarriage
- (ix) Diagnose retained products of conception
- (x) Counselling for failed pregnancy
- (xi) Diagnose ectopic pregnancy

(C) Menorrhagia

- (i) Identify submucous fibroid
- (ii) Identify intramural fibroid
- (iii) Identify subserous and pedunculated fibroid
- (iv) Identify adenomyosis

(D) Post-menopausal and inter menstrual bleeding

- (i) Measure endometrial thickness
- (ii) Identify atrophic endometrium
- (iii) Identify hyperplastic endometrium
- (iv) Identify endometrial polyps
- (v) Identify functional ovarian tumours

(E) Pelvic Mass

- (i) Identify mass as uterine
- (ii) Identify unilocular ovarian mass
- (iii) Identify complex ovarian mass
- (iv) Identify ascites.

(F) Reproductive Medicine

- (i) Identify cyclical changes in endometrium
- (ii) Identify cyclical changes in ovary
- (iii) Identify polycystic ovary
- (iv) Locate Intra-uterine Device or Intra-uterine System position in uterus

(G) Extra-Pelvic Scans

- (i) Identify normal placement of Implanon
- (ii) Locate non-palpable Implanon

(H) Contents - Section One

- (i) Instrumentations and basics
- (ii) Physics for practical applications
- (iii) Examination techniques
- (iv) Trans-abdominal and Trans-vaginal Scan

1. The knowledge base.—(1) Principles of ultrasound examination:

- (i) Physics
- (ii) Safety
- (iii) Machine set-up and operation
- (iv) Patient care
- (v) Principles of report writing
- (vi) Consent

- (2) The relevant principles of acoustics, attenuation, absorption, reflection, speed to sound;
- (3) The effect on tissues of pulsed and continuous wave ultrasound beams: biological effects, thermal and non-thermal; safety
- (4) Basic operating principles of medical instruments
- (5) Types of transducers

2. Skill sets.—(1) Use of ultrasound controls:

- (i) Signal processing – gray scale – time gain compensation, acoustic output relationship
- (ii) Artefacts, interpretation and avoidance – reverberation – side lobes – edge effects – registration – shadowing – enhancement
- (iii) Measuring systems – linear, circumference, area and volume – Doppler ultrasound – flow
- (iv) Imaging recording, storage and analysis
- (v) Interpretation of acoustic output information and its clinical relevance
- (vi) Patient information and preparation reporting

(I) Contents – Section Two

- (i) Ultrasound anatomy of the abdomen, pelvis and fetus
- (ii) Embryology or pathophysiology in short as applied to abd-pelvis

1. The knowledge base

- (i) Knowledge of normal ultrasound appearances of the endometrium, myometrium and ovaries throughout a menstrual cycle.

- (ii) Understanding of techniques to measure the uterus, endometrium.
 - (iii) Knowledge of normal ultrasound appearances of the ovaries and adnexa.
 - (a) **Gynaecological abnormalities: uterine**
 - (i) Knowledge of the ultrasound appearances of fibroids and adenomyosis
 - (ii) Knowledge of endometrial pathology.
 - (iii) Intra-uterine Contraceptive Device localization
 - (b) **Gynaecological abnormalities: ovarian lesions**
 - (i) Knowledge of the differential diagnosis of ovarian and para-ovarian lesions.
 - (ii) Knowledge of typical ultrasound findings of common ovarian appearances such as polycystic ovaries.
 - (iii) Knowledge of ultrasound features of ovarian cancer and the features of advanced disease.
 - (c) **Extraovarian lesions**
 - (i) Knowledge of the principles of conducting ultrasound examination in chronic pelvic pain.
 - (ii) Knowledge of typical morphological features of endometriosis, and pelvic adhesions.
 - (d) **Ultrasonography Anatomy of Abdomen**
 - (i) Knowledge Base – Normal appearance.
 - (ii) Abnormalities commonly found.
 - (iii) Reporting of Mass lesions.
 - (iv) Measurements – specific locations & Proper Techniques.
- 2. Skill sets**
- (i) Ability to consistently identify and examine the uterus, ovaries, adnexa and pouch of Douglas.
 - (ii) Ability to assess cyclical endometrial changes and endometrial responses to the combined pill and other hormonal preparations.
 - (iii) Ability to assess the uterine size and to accurately measure endometrial thickness.
 - (iv) Ability to assess ovarian volume and functional changes in the ovaries and adnexa during menstrual cycle: follicular appearances, variation in the morphology of corpora lutea, functional cysts, fluid in pouch of Douglas.
 - (v) Ability to diagnose uterine fibroids, measure their size and assess their relation to the endometrial cavity. Correlate ultrasound findings to clinical symptoms.
 - (vi) Ability to assess fibroids and adenomyosis and differentiate where possible.
 - (vii) Ability to interpret the measurement of endometrial thickness in the clinical context.
 - (viii) Ability to differentiate between focal and global endometrial thickness.
 - (ix) To be able to identify Infra-uterine Contraceptive Device and its location within the uterus.
 - (x) Ability to perform ultrasound examination combined with palpation in order to accurately identify the origin of pelvic lesion and interpret this in the clinical context.
 - (xi) Ability to assess the size of adnexal lesions including mean diameter and volume.

- (xii) Ability to approach the assessment of adnexal lesions in a systematic way. Familiarity with standardised terms and definitions to describe sonographic features of adnexal lesions.
 - (xiii) Ability to diagnose simple functional and haemorrhagic cysts, polycystic ovaries, dermoids and endometriomas based on subjective assessment alone.
 - (xiv) Ability to recognise abnormal pelvic fluid/ascites.
 - (xv) Ability to take a good clinical history in order to facilitate differential diagnosis of pelvic pain.
 - (xvi) Be able to assess tenderness and mobility of pelvic organs including the pouch of Douglas on transvaginal ultrasound scan.
 - (xvii) Ability to recognise ovarian endometriomas, hydrosalpinges, the consequences of pelvic adhesions and peritoneal pseudocysts on ultrasound scan.
 - (a) **(1) Gynaecological ultrasound**
 - (i) Accurate measurement of the
 - (ii) endometrium in the accepted sagittal plane
 - (iii) Assessment of the adnexal regions: accurate identification of the normal ovaries, normal fallopian tube, normal pelvic fluid
 - (iv) Accurate measurement of normal and abnormal adnexal structures: mean diameter and volume
 - (v) Recognise and evaluate common endometrial and myometrial abnormalities
 - (vi) Recognise and evaluate common ovarian abnormalities
 - (vii) Recognise and evaluate complex ovarian masses and refer on appropriately
 - (viii) Communicating normal results to patients
 - (ix) Communicating appropriate abnormal results to patients
 - (x) Producing written summary and interpretation of results
 - (xi) Issue structured written report
 - (xii) Arranging appropriate follow up or intervention
 - (b) **(2) Skill Set**
 - (i) Ability to consistently identify and examine Abdominal structures
 - (ii) Identify Normal
 - (iii) Identify Common Pathological Lesions
 - (iv) How and When to seek further opinion
- (b) Liver and Spleen or Biliary System or Gall Bladder or Pancreas**
Patient preparation and Scanning Techniques
—Sonographic Anatomy
- (i) **Liver** – Diffuse liver disease, Fatty Liver, Grades. Acute hepatitis, cirrhosis and portal hypertension, Focal Mass lesions—Cystic Lesions or Solid Lesions
 - (ii) **Spleen** – Splenomegaly or Focal splenic mass - Solid mass, cysts, subphrenic abscess
 - (iii) **Gall Bladder** – Cholelithiasis or GB filled with calculi or Atypical calculus or Pitfalls
 - (iv) **Pancreas** – Inflammatory Acute pancreatitis (pancreatic and extrapancreatic manifestation)
 - (a) Pseudocyst or Chronic Pancreatitis or Neoplasms (solid and cystic looking)

(c) PROSTATE

- (i) Sonographic anatomy (prostate, seminal vesicles)
- (ii) Technique (trans abdomina approach)
- (iii) To identify central zone & peripheral zone or Measurement of prostate volume
- (iv) Pathology
 - (a) Benign hypertrophy Prostatitis
 - (b) Prostatic abscess Cancer of prostate

(d) URINARY SYSTEM

Kidneys & ureters ... scanning technique

(e) KIDNEYS

- (i) Sonographic anatomy
- (ii) Echogenicity, corticomedullary demarcation, renal sinus, Hypertrophied
- (iii) Column of Bertin
- (iv) URETERS Congenital anomalies (agenesis, ectopia, duplex collecting system & ureterocele)
- (v) Hydronephrosis Renal calculus or Infection or Tumours or Mimics of calculus
- (vi) Nephrocalcinosis or Pyelonephritis, pyonephrosis, renal and perinephric abscess, chr. Pyelonephritis or Tuberculosis or Renal cell carcinoma, spectrum of sonographic appearance or Angiolipoma
- (vii) Benign Cystic lesions (simplecortical cyst, complex cortical cyst, parapelvic cyst)
- (viii) Polycystic kidney disease

(f) BLADDER

- (i) Bladder calculus, bladder volume measurement.
- (ii) Bladder wall (technique of thickness measurement).
- (iii) Bladder mass, cystitis.

(J) Contents — Section Three: Basics of obstetric scanning and interpretation in all trimesters – 3 Modules

I. Module 1 Early pregnancy: Trans-abdominal ultrasound examination of early pregnancy

The aims of the module;

- (i) For trainees to become familiar with ideal machine set up and use of the trans abdominal probe (including probe orientation)
- (ii) To gain competence in undertaking a basic 'dating scan' using trans abdominal scanning between 8-12 weeks gestation
- (iii) To encourage an acute awareness of what can and cannot be seen using the trans abdominal route in early pregnancy.

(a) Learning outcomes

To be able to carry out appropriate:

- (i) ultrasound identification of an intrauterine pregnancy
- (ii) ultrasound identification of cardiac activity
- (iii) basic first trimester biometry
- (iv) referral as required

(b) The knowledge base

- (i) Understand morphological features of normal early pregnancy.
- (ii) Understand physiology of cardiac activity in first trimester.
- (iii) Understand principles of gestational sac diameter and crown-rump length measurements.
- (iv) Understand the principles of differences between normal intra-uterine gestation sac and a pseudosac.
- (v) Understand diagnostic problems which may occur e.g. empty bladder, obese women and those with large uterine fibroids.
- (vi) Know when to refer for a trans-vaginal scan.

(c) Understand the diagnosis of multiple

- (i) pregnancy, chorionicity and amnionicity.
- (ii) Understand criteria to diagnose miscarriage.
- (iii) Understand the principles of ultrasound diagnosis of ectopic pregnancy.
- (iv) Understand the management of women with Pregnancy of Unknown Location.
- (v) Knowledge of clinical and ultrasound findings suspicious of molar.

(d) Skill sets

- (i) Ability to identify the features of a normal.
- (ii) gestational sac and confirm its intra-uterine location.
- (iii) Ability to measure gestational sac size and crown-rump length.
- (iv) Ability to identify early cardiac activity using B-mode.
- (v) Identify fetal number.
- (vi) Ultrasound diagnosis of early embryonic demise.
- (vii) Ultrasound assessment of a woman with suspected ectopic pregnancy.
- (viii) Ability to establish the diagnosis of multiple pregnancy with confidence and to assess chorionicity and amnionicity.
- (ix) Ability to diagnose early embryonic demise based on assessment of gestational sac size and/or crown-rump length. Identify, assess and measure retained products of conception in women with incomplete miscarriages.
- (x) Ability to correlate clinical, morphological and biochemical findings.
- (xi) Ability to evaluate adnexa in a systematic and effective way and to interpret the findings in a clinical context. Identify the site and the number of corporalutea. Identify tubal and non-tubal ectopic pregnancy and examine for the presence of a yolk sac or an embryo. Assess the amount and quality of fluid in the pouch of Douglas.
- (xiii) Seek help with confirmation of diagnosis and further management.
- (xiv) Recognise limits of competency.
- (xv) Know limits of own ability and when to refer for further opinion Accurate documentation of measurements.
- (xvi) Producing written summary and interpretation of results.
- (xvii) Communicating normal results to parents.
- (xviii) Communicating abnormal results to parents .
- (xix) Arranging appropriate referral, follow up or intervention.

II. Module 2 - Basic: Ultrasound assessment of fetal size, liquor and the placenta**(a) The aims of the module:**

To gain basic competences that are potentially useful in day-to-day obstetric practice, including lie, presentation, placental site and liquor assessment. Basic biometry techniques will be taught but competence to the level of 'independent practice' is not required

(b) The knowledge base**1. Biometry**

- (i) Awareness of the various lies and presentations
- (ii) Fetal growth or Physiology
- (iii) Pathology
 - (A) Maternal
 - (B) Placental
 - (C) Fetal
- (iv) Fetal biometry or Anatomical landmarks or Reference charts or Interpretation (including variability)
- (v) Calculation and value of:
 - (A) Ratios
 - (B) Estimated fetal weight

2. Amniotic fluid

- (i) Amniotic fluid volume or Physiology or Change with gestation or Pathology
- (ii) Ultrasound measurement
- (iii) Subjective vs objective
- (iv) Max vertical pocket or Amniotic Fluid Index
- (v) Reference charts
- (vi) Interpretation (including variability)
- (vii) Oligohydramnios
- (viii) Definition and associations
- (ix) Polyhydramnios
- (x) Definition and associations

3. Placenta

- (i) Ultrasound assessment of site
- (ii) Indication for Transabdominal and transvaginal ultrasound
- (iii) Placenta praevia
- (iv) Classification
- (v) Management

(c) Skill Sets

- (i) Accurate measurement of Bi-parietal Diameter, Head Circumference, Abdominal Circumference, Femure Length
- (ii) Accurate documentation of measurements and observations, including chart plotting
- (iii) Assessment of liquor volume
- (iv) Be able to perform and interpret assessment of Amniotic Fluid Volume, maximum vertical pool depth and Amniotic Fluid Index using ultrasound

- (v) Measurement of Amniotic Fluid Index
- (vi) Assessment of liquor volume
- (vii) Measurement of Maximal Vertical Pool Depth
- (viii) Assessment of placental position using the trans-abdominal route
- (ix) Arranging appropriate follow up or referral
- (x) Producing written summary and interpretation of results
- (xi) Communicating normal results to parents
- (xii) Maintains awareness of limitations of own competence

III. Module 3: Intermediate: Ultrasound of normal fetal anatomy**(a) The aims of the module:**

The overall aim of this module is to ensure that the trainee understands the indications for a fetal anatomy scan, is able to perform the scan safely and competently and to report the findings of the scan.

(b) Learning outcomes

The trainee should be able to:

- (i) take a proper clinical history.
- (ii) carry out ultrasound examination in the appropriate environment with respect to the patients' privacy, cultural and religious needs.
- (iii) understand the normal morphological ultrasound appearances of the fetus and its environment
- (iv) diagnose normal fetal anatomy
- (v) be aware of the normal anatomical variants
- (vi) understand the limits of their competence and the need to seek advice where appropriate
- (vii) Communicate the results to the parents
- (viii) write a structured report
- (ix) learn when to refer patients where appropriate.

(c) The knowledge base

- (i) Know anatomical landmarks for performing standard fetal measurements Bi-parietal Diameter, Head Circumference, Abdominal Circumference, Femure Length
- (ii) Recognise normal appearance of fetal structures and appreciate different appearance at different gestations
- (iii) Know the detection rates of common anomalies
- (iv) Provide parents with necessary information in a form they understand
- (v) Communicate scan findings and information given to parents to other health professionals.

(d) Skill sets

- (i) Identify fetal position within uterus
- (ii) Be able to move probe with purpose to identify
- (iii) fetal structures
- (iv) Be able to consistently and systematically identify the features described in an "optimal" anomaly scan. Be able to perform standard fetal measurements

Bi-parietal Diameter, Head Circumference, Abdominal Circumference, Femure Length including and also transcerebellar diameter, ventricular a trial diameter and Antero-posterior diameter of the renal pelvis

- (v) Identify placental site
- (vi) Recognise limits of competency
- (vii) Recall patients appropriately for further scans if structures not seen clearly
- (viii) Accurate measurements of Bi-parietal Diameter, Head Circumference, Abdominal Circumference, Femure Length, Transverse Cerebral Diameter and lateral atrial diameter of the cerebral ventricles
- (ix) Confirm normal anatomy of head and face
- (x) Confirm normal anatomy of spine
- (xi) Confirm normal anatomy of heart and chest
- (xii) Confirm normal anatomy of abdomen
- (xiii) Confirm normal anatomy of limbs
- (xiv) Perform full anomaly scan
- (xv) Recognise common structural anomalies
- (xvi) Locate and assess placenta
- (xvii) Assess liquor volume
- (xviii) Provide parents with information about
 - (xix) Normal scan findings
 - (xx) Abilities and limitations of ultrasound
 - (xxi) To be aware of the limitations of this technique and know when to refer
 - (xxii) To be able to discuss with parents the possibility of an abnormality and the need for a further opinion.

(K) Contents – Section Four

1. Introduction to the problem of declining child sex ratio and provisions of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act.

Continuous decline in child sex ratio since 1961 Census is a matter of concern for the country. Beginning from 976 in 1961 Census, it declined to 927 in 2001. As per Census 2011 the Child Sex Ratio (0-6 years) has dipped further to 919 against 927 girls per thousand boys recorded in 2001 Census. Child sex ratio has declined in 18 States and 3 UTs and except for the States of Himachal Pradesh (909), Punjab (846), Chandigarh (880), Haryana (834), Mizoram (970), Tamil Nadu (943), Karnataka (948), Delhi (871), Goa (942), Kerala (964), Gujarat (890), Arunachal Pradesh (972), and Andaman & Nicobar Islands (968) showing marginal improvement, rest of the 21 States/UTs have shown decline.

“The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of sex Selection) Act”

“An Act to provide for the prohibition of sex selection, before or after conception, and for regulation of pre-natal diagnostic techniques for the purposes of detecting 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.”

2. Implementation of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994:

The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act was enacted on September 20, 1994 and the Act was further amended in 2003. The Act provides for the prohibition of sex selection, before or after conception, and for regulation of pre-natal diagnostic techniques for the purposes of detecting genetic abnormalities or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex linked disorders and for the prevention of their misuse for sex determination leading to female foeticide and for matters connected therewith or incidental thereto.

The Act is implemented through the following implementing bodies:

- (i) Central Supervisory Board
- (ii) State Supervisory Boards and Union Territory Supervisory Boards
- (iii) Appropriate Authority for the whole or a part of the State or Union Territory
- (iv) State Advisory Committee and Union Territory Advisory Committee
- (v) Advisory Committees for designated areas (part of the State) attached to each Appropriate Authority.
- (vi) Appropriate Authorities at the District and Sub-District levels

3. Registration:

Appropriate Authority of the district is responsible for registration of ultrasound diagnostic facilities.

4. Application fee:

- (1) Rs. 25000.00 for Genetic Counselling Centre, Genetic laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre.
- (2) Rs. 35000.00 for an institute, hospital, nursing home, or any place providing jointly the service of Genetic Counselling Centre, Genetic laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre or any combination thereof.

5. Mandatory Displays at ultrasound center:

- (1) Pre-conception and Pre-natal Diagnostic Techniques (PC and PNNT) Certificate: It is mandatory for every clinic or facility or hospital etc. registered under the Pre-conception and Pre-natal Diagnostic Techniques Act to display the certificate of registration at a conspicuous place at such Centre, Laboratory or Clinic.
- (2) Signage, board or banner in English & local language indicating that foetal sex is not disclosed at the concerned facility.
- (3) Copy of the Pre-conception and Pre-natal Diagnostic Techniques Act must be available in every ultrasound center

6. Renewal of registration

- (1) Every certificate of registration is valid for a period of 5 years
- (2) Renewal of registration to be done 30 days before the date of expiry of the certificate of registration.

7. Mandatory maintenance of records: Register showing in serial order:

- (1) Names and addresses of men or women subjected to *pre-natal diagnostic procedure or test*,
- (2) Names of their spouses or fathers;
- (3) Date on which they first reported for such counselling, procedure or test.
- (4) A monthly report should be submitted to the Appropriate Authority regularly, before the 5th of every month. A copy of same monthly reports with the

8. Preservation of the following duly completed forms

- (i) Form F
- (ii) Referral Slips of Doctors
- (iii) Forms of consent
- (iv) Sonographic plates or slides

9. Record storage:

All above records should be preserved for 2 years.

10. Powers of Appropriate Authority:

- (1) Appropriate Authority can enter freely into any clinic or facility for search and seizure.
- (2) Examine and inspect of registers, records including consent forms, referral slips, Forms, sonographic plates or slides and equipment like ultrasonography machines.
- (3) To ensure presence of at least two independent witnesses of the same locality or different locality during the search.

11. For further Do's and Don'ts about following the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act and rules a Handbook of Pre-conception and Pre-natal Diagnostic Techniques Act and rules with Amendments published by Ministry of Health, Government of India has made available online on www.pndt.nic.in

SCHEDULE II**LOGBOOK AND ASSESSMENT****1. The Logbook**

The Logbook records the training activity, tutorials and self-directed learning undertaken and competencies achieved. Maintenance and regular review of the logbooks during interim assessments will allow the Principal Trainer and Trainee to monitor progress and identify deficiencies over the course of training. The Trainer will sign the appropriate sections of the Logbook documents with regard to attendance, skill and competence. It is imperative that all participants appreciate that the Trainee's progress has to meet standards that satisfy the Trainers. At the end of the training programme, the Principal Trainer has to certify that the competencies and skills attained by the Trainee are to his/her satisfaction.

(1) Training Plan Level 1 exercise to be performed under direct supervision:

At this initial assessment, a training plan should be agreed between the Principal Trainer and the Trainee, using the competency, skills and attitudes lists to set the learning objectives. (This should include, identifying a theory course to be attended within 6 months of induction assessment, if not already undertaken.) The initial learning objectives and the activity plan to meet these should be tailored to the individual learning needs of the Trainee. Subsequent learning objectives should be set at interim assessments until the Trainee has attained all the competencies, skills and attitudes on the lists.

It is the Trainee's responsibility to undertake this planned learning. The Principal Trainer should guide this, but need not undertake all training themselves.

In addition to the recording of competence, the logbook also contains sections for the recording of ultrasound images and basic clinical details of clients seen by the trainee. The ultrasound images should be of high quality and demonstrate aspects of the ultrasound scan which are pertinent to the clinical case and should have been obtained

by the trainee. The trainee should review suitable images with the Trainer, prior to attaching them to the logbook.

This logbook is intended to record experience of ultrasound imaging in clinics where clients are referred for ultrasound imaging as part of the management of their abdomino-pelvic and gynecological conditions (early pregnancy clinics, pre-abortion assessment clinics, etc) either in hospital or community setting.

It also:

- (a) Provides a summary of the syllabus in the form of a list of necessary competencies.
- (b) Records the outcomes of the learning objectives agreed between you and your Trainers.
- (c) Provides a record of your achievements as you attain competence in the required areas.
- (d) Records the certified assessment of your competence when applying for the Certificate.
- (e) Provide a permanent record of interesting cases to act as a reference for future practice.

(2) Minimum Number of Scans for Level-I Training (Total 200 cases)**Obstetric Scans**

Viable Pregnancies	10
Non-Viable Pregnancies	10
Normal Biometry	10
Growth Restrictions	10
Abnormal Pregnancy	10 (ectopic or multiple etc.)
Gynaec	10
IUCD's	05
Fibroids	10
Ovarian Cysts	10
Gynaec Disorders	10

Non-Obstetric Scans

Normal abdominal Scan	20
Gall Stone Disease	10
Extra hepatic Biliary Channel	05
Hepatic Solid Masses	05
Hepatic Cystic Lesions	05
Pancreas	05
Urinary	25
Normal Scan	10
Cystic lesions of Kidney including Hydronephrosis	05
Solid lesions of Kidneys	05
Ureteric and Bladder Stones	05
Prostate	05

Observations—

Trans-vaginal Scan	10
Color Doppler Studies Obstetric	10

2. Assessment

As well as the initial assessment, the Principal Trainer must perform at least one interim assessment to check the Trainee's progress and the summative (final) assessment of competence. The Principal Trainer has to certify that the competencies and skills attained by the Trainee are to his/her satisfaction.

It is the responsibility of the independent examiner to be nominated by Director, Medical Education Department of the concerned State to certify final competence, in order to exit the training programme .

(1) Guidelines for Assessors

- Assessors may be Ultrasonographers, Obstreticians or Gynaecologists or doctors experienced in ultrasonography.
- Assessor should explain to the person being assessed, that the purpose of this exercise is to assess technical competence.
- The trainee should perform the procedure based on his/her usual practice. The trainee and trainer should fill in the forms separately and use them to inform discussion following observation of the trainee. The assessment is designed to assess technical skills. It enables discussion on technique and will allow discussion on why the trainee acted as she/he did.
- It is planned that each trainee should be assessed by Objective Structured Assessment of Technical Skills at least twice in a training programme; by different assessors, one of whom should be the Independent Examiner, as part of the summative assessment.
- Trainees must already have achieved competence (direct supervision), in the procedure being evaluated.

For each procedure, the following must be completed:

- Itemised Checklist Score
- Objective Structured Assessment of Technical Skills assessment sheet

It is not necessary to obtain written consent from patients, but it would be prudent to say that the Trainee is partaking in an assessment with full supervision. Patients may choose not to be part of the assessment process.

3 copies of the forms should be kept;

- One for the trainee's portfolio
- One for the Principal Trainer
- One to go back to the Faculty with all forms when the certificate is applied for.

(2) OBJECTIVE STRUCTURED ASSESSMENT OF TECHNICAL SKILLS (OSATS)

(A) BASIC SKILLS Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Machine set-up			
Counselling for scan			
Decide transabdominal vs.			

(A) BASIC SKILLS Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Transvaginal route			
Choice of probe			
Patient positioning			
Orientation			
Identify normal Endometrium			
Identify normal Myometrium			
Identify normal ovaries			
Measure cervical length			
Recording images			
Note keeping			

Special Remarks

(B). EARLY PREGNANCY Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Confirm viability			
Date pregnancy			
Diagnose corpus luteum cyst			
Diagnose multiple pregnancy			
Identify retroplacental haematoma			
Diagnose anembryonic pregnancy			
Diagnose missed miscarriage			
Diagnose retained products of conception			
Counselling for failed pregnancy			
Diagnose ectopic pregnancy			

Special Remarks

(C). MENORRHAGIA Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Identify submucous fibroid			
Identify intramural fibroid			
Identify subserous and pendunculated fibroid			
Identify adenomyosis			

Special Remarks

(D). POST-MENOPSA AND INTER-MENSTRUAL BLEEDING Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Measure endometrial thickness			
Identify atrophic endometrium			
Identify hyperplastic endometrium			
Identify endometrial polyps			
Identify functional ovarian tumours			

Special Remarks

(E) PELVIC MASS Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Identify mass as uterine			
Identify unilocular ovarian mass			
Identify complex ovarian mass			
Identify ascites			

Special Remarks

(F). REPRODUCTIVE MEDICINE Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
Identify cyclical changes in endometrium			

Identify cyclical changes in ovary			
Identify polycystic ovary			
Locate Intra-uterine Device or Intra-uterine System position in uterus			
EXTRA PELVIC SCANS			
Identify normal placement of Implanon			
Locate non-palpable Implanon			

Special Remarks

(G). GENERAL ABDOMEN Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
LIVER AND SPLEEN or BILIARY SYSTEM			
Patient preparation and Scanning Techniques-Sonographic Anatomy			
Diffuse liver disease			
Fatty Liver, Grades.			
Acute hepatitis, cirrhosis and portal hypertension			
Focal Mass lesions - Cystic Lesions or Solid Lesions			
Spleen - Splenomegaly or Focal splenic mass - Solid mass, cysts, subphrenic abscess			

Special Remarks

(H). GENERAL ABDOMEN Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	
URINARY SYSTEM			
Kidneys & ureters ... scanning technique			
Sonographic anatomy			
Echogenicity, corticomedullary demarcation, renal sinus, Hypertrophied			
Column of Bertin			

URETERS Congenital anomalies (agenesis, ectopia, duplex collecting system & urethrocele)			
Hydronephrosis or Renal calculus or Infection or Tumours or Mimics of calculus			
Nephrocalcinosis or Pyelonephritis, pyonephrosis, renal & perinephric abscess, chr. Pyelonephritis or Tuberculosis or Renal cell carcinoma, spectrum of sonographic appearance or Angiolipoma			
Benign Cystic lesions (simple cortical cyst, complex cortical cyst, parapelvic cyst)			
Polycystic kidney disease			

Special Remarks

(I) GENERAL ABDOMEN Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	

BLADDER

Bladder calculus, bladder volume measurement.			
Bladder wall (technique of thickness measurement)			
Bladder mass, cystitis			

Special Remarks

(J) GENERAL ABDOMEN Skill	Level 1	Level 2	Trainer to sign and date when competence achieved
	Supervised	Independent	

GALL BLADDER or PANCREAS

Gall Bladder- Cholelithiasis			
GB filled with calculi or Atypical calculus or Pitfalls			
Pancreas - Inflammatory Acute pancreatitis pancreatic and extra-pancreatic manifestation			

Pseudocyst or Chronic Pancreatitis or Neoplasms (solid and cystic looking)			
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Special Remarks

(K) GENERAL ABDOMEN Skill	Level 1	Level 2	Preceptor to sign and date when competence achieved
	Supervised	Independent	
PROSTATE			
Sonographic anatomy (prostate, seminal vesicles)			
Technique (transabdominal approach)			
To identify central zone and peripheral zone or Measurement of prostate volume			
Pathology - Benign hypertrophy Prostatitis Prostatic abscess - Cancer of prostate			

Special Remarks**GUIDELINES FOR ASSESSMENT FOR FINAL EXAMINATION****Minimum pass marks - For practicals 60 and Theory 50****I. THEORY ASSESSMENT**

- 100 marks - two hours
- 50 multiple choice questions of one mark each = 50 marks
- 10 short answers with five marks each = 50 marks
- Short Question will have a defined space for the candidate to fit answer.

II. PRACTICAL ASSESSMENT

- 20 marks for log book
- 50 marks for demonstrations
- 30 marks viva

Note: The examiner can choose any FIVE of these TEN for demo and allot 10 marks each

Step 1: Preparation

- 1.1 Equipment preparation
- 1.2 Patient preparation
- 1.3 Operator preparation
- 1.4 Expose the lower abdomen and apply the gel
- 1.5 Select the transducer

Notes

Step 2: Commence the growth and high-risk pregnancy scanning protocol

2.1 Patient position

2.2 Scan plane

2.2 Transabdominal scan plane

Endovaginal scan plane

2.3 Standard second and third trimester protocol image requirements

1. Fetal lie, life, number, presentation, and *situs*

2. Maternal uterus and adnexae

3. Amniotic fluid and placental location

4. Fetal biometry

5. Fetal anatomy

Step 3: Overview of second and third trimester routine ultrasound examination

Step 4: Perform targeted scan relevant to clinical condition of fetus and/or mother

4.1 Scan for multiple pregnancy

Step 5: Scan for intra-uterine growth restriction

5.1 Fetal biometry, growth, and weight

Step 6: Scan for amniotic fluid and membranes

6.1 Calculate the amniotic fluid volume

Step 7: Scan for placenta and umbilical cord abnormalities

7.1 Placenta

7.2 Umbilical cord

Step 8: Scan for fetal biophysical profile

Step 9: Scan for fetal complications of maternal disease

9.1 Fetal hydrops

9.2 Maternal diabetes

9.3 Maternal hypertension and pre-eclampsia

9.4 Other maternal diseases

**Step 10: Demonstrate - to asses general abdominal scan - maternal liver/gall bladder/
kidneys**

III. VIVA - 30 marks on three case situations

Clinicosonographic co-relation

video clip and case studies

IV. CASE STUDY

Case Number:

Date:

Preliminary data

Ultrasonography Findings

Impressions

Key Learnings

**CIVIL, CRIMINAL, COMMERCIAL,
LABOUR & SERVICES****A**

- A-20. Aadhaar (Targeted Delivery of Financial and other Subsidies, Benefits and Services) Act, 2016 with Order and Regulations
- A-17. Actuaries Act, 2006 alongwith Allied Rules
- A-1. Administration of Evacuee Property Act, 1950 with Rules, 1950
- A-2. Administrative Tribunals Act, 1985 along with CAT (Procedure) Rules, 1987, CAT Rules of Practice, 1993 and Contempt of Courts (C.A.T.) Rules, 1992
- A-22. Admiralty (Jurisdiction and Settlement of Maritime Claims) Act, 2017 with Rules & Order
- A-3. Advocates Act, 1961
- A-4. Advocates' Welfare Fund Act, 2001
- A-5. Aircraft Act, 1934 along with allied Rules
- A-6. Air Force Act, 1950 along with allied Act and Rules
- A-7. Air (Prevention and Control of Pollution) Act, 1981 along with Rules, 1982
- A-15. Airport Authority of India Act, 1994 along with Rules and Regulations
- A-8. Ancient Monuments and Archaeological Sites and Remains Act, 1958 along with allied Acts & Rules
- A-21. Anti-Hijacking Act, 2016 with Rules, 2017
- A-9. Antiquities and Art Treasures Act, 1972 along with Rules, 1973
- A-10. Apprentices Act, 1961 along with Rules
- A-11. Arbitration and Conciliation Act, 1996 along with Scheme, 1996
- A-19. Architects Act, 1972, along with Rules and Regulations
- A-12. Armed Forces (Special Power) Act, 1958 along with allied Acts
- A-18. Armed Forces Tribunal Act, 2007 along with allied Rules
- A-13. Arms Act, 1959 along with Rules, 2016
- A-14. Army Act, 1950 with Rules, 1954
- A-16. Atomic Energy Act, 1962 with allied Rules

B

- B-1. Bankers' Books Evidence Act, 1891
- B-2. Banking Companies (Acquisition and Transfer of Undertakings) Act, 1970 along with allied Act and Schemes
- B-3. Banking Regulation Act, 1949 along with allied Rules and Scheme
- B-4. Bar Council of India Rules along with allied Rules and Advocates Act, 1961
- B-5. Beedi and Cigar Workers (Conditions of Employment) Act, 1966 along with Welfare Cess and Welfare Fund Act and Rules
- B-6. Prohibition of Benami Property Transactions Act, 1988 [Earlier Known as Benami Transactions (Prohibition) Act, 1988] with Rules, 2016
- B-7. Biological Diversity Act, 2002 along with Rules, 2004
- B-13. Black Money (Undisclosed Foreign Income and Assets) and Imposition of Tax Act, 2015
- B-8. Boilers Act, 1923 along with allied Rules
- B-9. Bonded Labour System (Abolition) Act, 1976 along with Rules, 1976

- B-10. Border Security Force Act, 1968 along with allied Rules
- B-11. Building and Other Construction Workers (Regulation of Employment and Conditions of Service) Act, 1996 along with Rules, 1998 with Cess Act and Rules
- B-12. Bureau of Indian Standards Act, 1986 along with Rules, Regulations & Order
- B-14. Bureau of Indian Standards Act, 2016 along with Rules, Regulations & Order

C

- C-1. Cable Television Networks (Regulation) Act, 1995 along with allied Rules & Regulations
- C-2. Cantonments Act, 2006 with allied Rules
- C-4. Carriage by Air Act, 1972 *see* Carrier Laws (Land • Sea • Air)
- C-44. Carriage by Road Act, 2007
- C-4. Carriage of Goods by Sea Act, 1925 *see* Carrier Laws (Land • Sea • Air)
- C-4. Carriers Act, 1865 *see* Carrier Laws (Land • Sea • Air)
- C-4. Carrier Laws (Land • Sea • Air)
- C-5. Cattle Trespass Act, 1871
- C-63. Census Act, 1948 with Rules, 1990
- C-43. Central Educational Institutions (Reservation in Admission) Act, 2006
- C-48. Central Electricity Authority Regulations
- C-49. Central Electricity Regulatory Commission Rules and Regulations
- C-6. Central Excise Act, 1944
- C-7. Central Industrial Security Force Act, 1968 along with Rules
- C-8. Central Reserve Police Force Act, 1949 along with Rules, 1955
- N-6. Central Road and Infrastructure Fund Act, 2000 *see* National Highways Act, 1956 along with allied Acts & Rules
- C-9. Central Sales Tax Act, 1956 along with Rules, 1957
- C-10. Central Vigilance Commission Act, 2003
- C-11. Charitable and Religious Trusts Act, 1920 along with Charitable Endowments Act, 1890 and Religious Endowments Act, 1863
- C-11. Charitable Endowments Act, 1890 *see* Charitable and Religious Trusts Act, 1920
- C-52. Chartered Accountants Act, 1949
- C-42. Chemical Weapons Convention Act, 2000 along with allied Rules
- C-12. Child and Adolescent Labour (Prohibition and Regulation) Act, 1986 along with Rules, 1988 and Children (Pledging of Labour) Act, 1933
- C-13. Child Marriage Restraint Act, 1929
- C-14. Chit Funds Act, 1982
- C-15. Christian Marriage Act, 1872
- C-16. Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 along with allied Rules
- C-17. Cine-Workers and Cinema Theatre Workers (Regulation of Employment) Act, 1981 along with allied Act and Rules
- C-18. Cinematograph Act, 1952 along with Cinematograph (Certification) Rules, 1983

- C-19. Citizenship Act, 1955 along with Citizenship Rules, 2009
- C-20. Civil Defence Act, 1968 along with Rules and Regulations
- C-50. Civil Liability for Nuclear Damage Act, 2010 with Rules, 2011
- C-47. Clinical Establishments (Registration and Regulation) Act, 2010 with Rules, 2012
- C-21. Code of Civil Procedure, 1908
- C-23. Code of Civil Procedure, 1908 with State Amendments (Hb)
- C-45. Code of Civil Procedure, 1908 with State & High Court Amendments with Letters Patent (Hb)
- C-24. Code of Criminal Procedure, 1973
- C-26. COFEPOSA Act, 1974 and SAFEMFOP Act, 1976 with Rules, 2006
- C-51. Coinage Act, 2011
- C-59. Commercial Courts Act, 2015 [Earlier known as Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act, 2015]
- C-46. Collection of Statistics Act, 2008 with Rules, 2011
- C-41. Commission for Protection of Child Rights Act, 2005 along with Rules
- C-27. Commissions of Inquiry Act, 1952 along with Rules, 1972
- C-28. Commission of Sati (Prevention) Act, 1987 along with Rules
- C-29. Companies Act, 2013
- C-57. Companies Act, 2013 with allied Companies Rules along with Companies (Removal of Difficulties) Orders
- C-58. Companies (Indian Accounting Standards) Rules, 2015
- C-53. Company Secretaries Act, 1980
- C-30. Competition Act, 2002 with allied Rules and Regulations
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- C-33. Consumer Protection Act, 1986 along with Rules, 1987 and Regulations, 2005
- C-34. Contempt of Courts Act, 1971 along with Rules to Regulate Proceedings for Contempt of the Supreme Court, 1975
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- D-1. Dangerous Machines (Regulation) Act, 1983 along with Rules, 2007
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- D-4. Divorce Act, 1869
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- D-6. Dowry Prohibition Act, 1961 along with Rules
- D-12. Dramatic Performances Act, 1876
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- G-1. Gas Cylinders Rules, 2016 along with allied Rules and Orders
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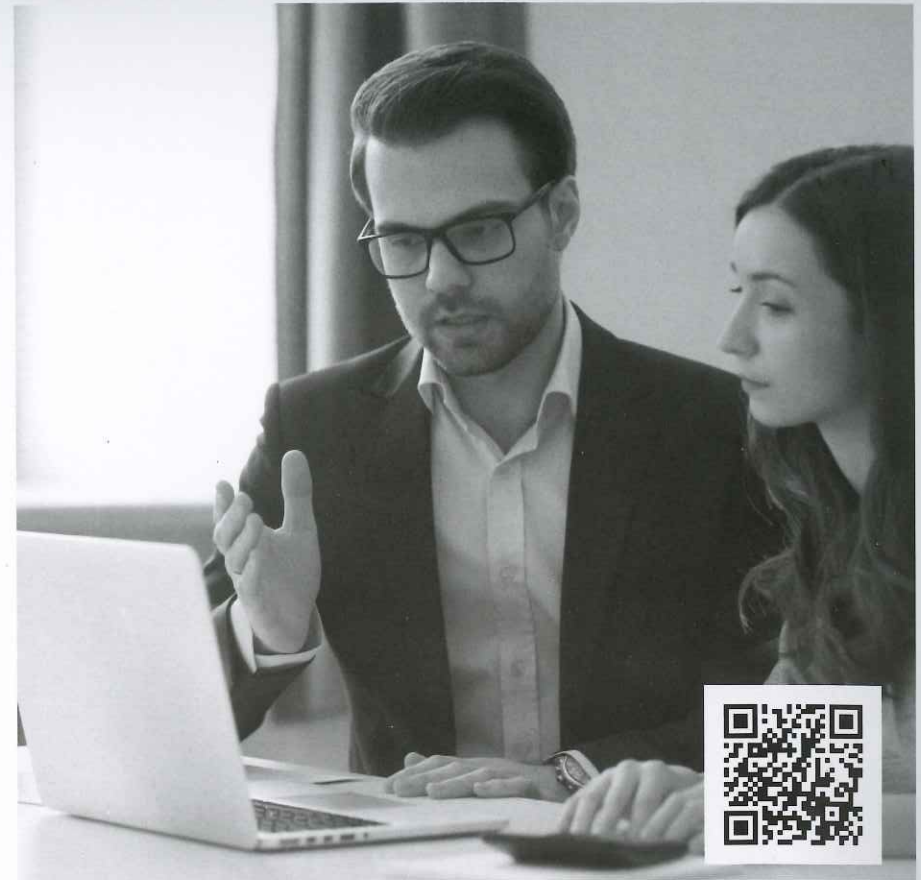
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