

THE PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) ACT, 1994

ACT NO. 57 OF 1994

[20th September, 1994]

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

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

(3) It shall come into force on such date 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;
- (c) "Genetic Counseling Centre" means an institute, hospital, nursing home or any place, by whatever name called, which provides for genetic counselling to patients;
- (d) "Genetic Clinic" means a clinic, institute, hospital, nursing home or any place, by whatever name called, which is used for conducting pre-natal diagnostic procedures;
- (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;
- (f) "Gynecologist" means a person who possesses a post- graduate qualification in gynecology and obstetrics;
- (g) "Medical geneticist" means a person who possesses a degree or diploma or certificate in medical genetics in the field of pre-natal diagnostic techniques or has experience of not less than two years in such field after obtaining--
 - (i) any one of the medical qualifications recognised under the Indian Medical Council Act, 1956 (102 of 1956); or
 - (ii) a post-graduate degree in biological sciences;
- (h) "Pediatrician" means a person who possesses a post- graduate qualification in pediatrics;
- (i) "pre-natal diagnostic procedures" means all gynecological or obstetrical or medical procedures such as ultrasonography foetoscopy, taking or removing samples of amniotic fluid, chorionic villi, blood or any tissue of a pregnant woman for being sent to a Genetic Laboratory or Genetic Clinic for conducting pre-natal diagnostic test;
- (j) "pre-natal diagnostic techniques" includes all pre-natal diagnostic procedures and pre-natal diagnostic tests;
- (k) "pre-natal diagnostic test" means ultrasonography or any test or analysis of amniotic fluid, chorionic villi, blood or any tissue of a pregnant woman conducted to detect genetic or metabolic disorders or chromosomal abnormalities or congenital anomalies or haemoglobinopathies or sex-linked diseases;
- (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.

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

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;
- (3) no pre-natal diagnostic techniques shall be used or conducted unless the person qualified to do so is satisfied that any of the following conditions are fulfilled, namely:--
- (i) age of the pregnant woman is above thirty-five years;
 - (ii) the pregnant woman has undergone of two or more spontaneous abortions or foetal loss;
 - (iii) the pregnant woman had been exposed to potentially teratogenic agents such as drugs, radiation, infection or chemicals;

- (iv) the pregnant woman has a family history of mental retardation or physical deformities such as spasticity or any other genetic disease;
- (v) any other condition as may be specified by the Central Supervisory Board;

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

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

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.

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;
- (c) two members to be appointed by the Central Government to represent the Ministries of Central Government in charge of Woman and Child Development and of Law and Justice, ex-officio;
- (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;
 - (ii) eminent gynaecologists and obstetricians;
 - (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; and

(b) in case of appointment under clause (g) of the said subsection, 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 or 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—

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

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

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

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

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,--

- (a) when appointed for the whole of the State or the Union territory, of or above the rank of the Joint Director of Health and Family Welfare; and
- (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; and
- (d) to seek and consider the advice of the Advisory Committee, constituted under sub-section (5), on application for registration and on complaints for suspension or cancellation of registration.

(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.

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

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

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

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

CHAPTER VI

REGISTRATION OF GENETIC COUNSELLING CENTRES, GENETIC LABORATORIES AND GENETIC CLINICS

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

(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.

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

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

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

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

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

20. Cancellation or suspension of registration.- (1) The Appropriate Authority may *suo moto*, or on complaint, issue a notice to the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic to show cause why its registration should not be suspended 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

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

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

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

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

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.

(2) The name of the registered medical practitioner who has been convicted by the court under sub-section (1), shall be reported by the Appropriate Authority to the respective State Medical Council for taking necessary action including the removal of his name from the register of the Council for a period of two years for the first offence and permanently for the subsequent offence.

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

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

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

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

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

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

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

(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.

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--

- (i) the minimum qualifications for persons employed at a registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic under clause (1) of section 3;
- (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;
- (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;
- (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-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) RULES, 1996

1. Short title and commencement.- (1) These rules may be called the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996.

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

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

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

3. Minimum requirements.- (1) The minimum qualifications of the employees, the minimum equipment and minimum place for a Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic shall be as specified in Schedules I, II and III.

(2) Where an institute, hospital, nursing home, or any place, by whatever name called, provides services jointly of Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic, or any combination of these, it shall conform to the requirements as specified in Schedules I, II and III.

4. Registration of Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic.- (1) An application for registration shall be made to the Appropriate Authority, in duplicate, in Form A.

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

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

- (a) Rs.2000.00 for Genetic Counselling Centre;
- (b) Rs.3000.00 for Genetic Laboratory;
- (c) Rs.3000.00 for Genetic Clinic; and
- (d) Rs.4000.00 for an institute, hospital, nursing home, or any place providing jointly the services of a Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic or any combination of such Centre, Laboratory or Clinic.

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

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

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

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

(3) If, after enquiry and after giving an opportunity of being heard to the applicant and having regard to the advice of the Advisory Committee, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of the Act and these rules, it shall, for the reasons to be recorded in

writing, reject the application for registration and communicate such rejection to the applicant as specified in Form C.

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

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

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

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

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

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

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

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

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

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

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

9. Maintenance and preservation of records.- (1) Every Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic shall maintain a register showing, in serial order, the names and addresses of the women given genetic counseling, subjected to pre-natal diagnostic procedures or pre-natal diagnostic tests, the names of their husbands or fathers and the date on which they first reported for such counseling, procedure or test.

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

(3) The record to be maintained by every Genetic Laboratory, in respect of each woman subjected to any pre-natal diagnostic test, shall be as specified in Form E.

(4) The record to be maintained by every Genetic Clinic, in respect of each woman subjected to any pre-natal diagnostic procedure, shall be as specified in Form F.

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

(6) All case related records, forms of consent, laboratory results, microscopic pictures, sonographic plates or slides, recommendations and letters shall be preserved by the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic for a period of two years from the date of completion of

counseling, pre-natal diagnostic procedure or pre-natal diagnostic test, as the case may be. In the event of any legal proceedings, the records shall be preserved till the final disposal of legal proceedings, or till the expiry of the said period of two years, whichever is later.

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

10. Conditions for conducting pre-natal diagnostic procedures.- (1) Before conducting any pre-natal diagnostic procedure, a written consent, as specified in Form G, in a language the pregnant woman understands, shall be taken from her:

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

11. Facilities for inspection.- Every Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic shall afford reasonable facilities for inspection of the place, equipment and records to the Appropriate Authority or to any other person authorized by the Appropriate Authority in this behalf.

12. Procedure for search and seizure.- (1) The Appropriate Authority or any officer authorized in this behalf may enter and search at all reasonable times any Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, in the presence of two or more independent and respectable persons for the purposes of Section 30.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SCHEDULE I

[See Rule 3 (1)]

REQUIREMENTS FOR REGISTRATION OF A GENETIC COUNSELLING CENTRE

A. PLACE

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

B. EQUIPMENT

Educational charts/models.

C. EMPLOYEES

Any one of the following-

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

SCHEDULE II

[See Rule 3(1)]

REQUIREMENTS FOR REGISTRATION OF A GENETIC LABORATORY

A. PLACE

A room with adequate space for carrying out tests.

B.EQUIPMENT

These are categorized separately for each of the under-mentioned studies.

Chromosomal studies:

- (1) Laminar flow-hood with ultraviolet and fluorescent light or other suitable culture hood.
- (2) Photo-microscope with fluorescent source of light.
- (3) Inverted microscope.
- (4) Incubator and oven.
- (5) Carbon-dioxide incubator or closed system with 5% CO₂ atmosphere.
- (6) Autoclave.
- (7) Refrigerator.
- (8) Water bath.
- (9) Centrifuge.
- (10) Vortex mixer.
- (11) Magnetic stirrer.
- (12) PH meter.
- (13) A sensitive balance (preferable electronic) with sensitivity of 0.1 milligram.
- (14) Double distillation apparatus (glass).

Biochemical studies:

(requirements according to tests to be carried out)

- (1) Laminar flow-hood with ultraviolet and fluorescent light or other suitable culture hood.
- (2) Inverted microscope.
- (3) Incubator and oven.
- (4) Carbon-dioxide incubator or closed system with 5% CO₂ atmosphere.
- (5) Autoclave.
- (6) Refrigerator.
- (7) Water bath.
- (8) Centrifuge.
- (9) Electrophoresis apparatus and power supply.
- (10) Chromatography chamber.
- (11) Spectro-photometer and Elisa reader or Radio-immunoassay system (with gamma betacounter) or fluorometer for various biochemical test.
- (12) Vortex mixer.
- (13) Magnetic stirrer.
- (14) PH meter.
- (15) A sensitive balance (preferable electronic) with sensitivity of 0.1 milligram.
- (16) Double distillation apparatus (glass).
- (17) Liquid nitrogen tank.

Molecular studies:

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

- (8) Electrophoresis apparatus and power supply.
- (9) Vortex mixer.
- (10) Magnetic stirrer.
- (11) PH meter.
- (12) A sensitive balance (preferable electronic) with sensitivity of 0.1 milligram.
- (13) Double distillation apparatus (glass).
- (14) P.C.R. machine.
- (15) Refrigerated centrifuge.
- (16) U.V. Illuminator with photographic attachment or other documentation system.
- (17) Precision micropipettes.

C.EMPLOYEES

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

SCHEDULE III

[See Rule 3(1)]

REQUIREMENTS FOR REGISTRATION OF A GENETIC CLINIC

A.PLACE

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

B.EQUIPMENT

- (1) Equipment and accessories necessary for carrying out clinical examination by an obstetrician/gynaecologist.
- (2) Equipment, accessories necessary for other facilities required for operations envisaged in the Act.
 - (a) An ultra-sonography machine.*
 - (b) Appropriate catheters and equipment for carrying out chorionic villi aspirations per vagina or per abdomen.*
 - (c) Appropriate sterile needles for amniocentesis or cordocentesis.*
 - (d) A suitable foetoscope with appropriate accessories for foetoscopy, foetal skin or organ biopsy or foetal blood sampling shall be optional.

(* These constitute the minimum requirement of equipment for conducting the relevant procedure)

- (3) Equipment for dry and wet sterilization.
- (4) Equipment for carrying out emergency procedures such as evacuation of uterus or resuscitation in case of need.

C.EMPLOYEES

- (1) A gynaecologist with adequate experience in pre-natal diagnostic procedures (should have performed at least 20 procedures under supervision of a gynaecologist experienced in the procedure which is going to be carried out, for example chorionic villi biopsy, amniocentesis, cordocentesis and others indicated at B above).
- (2) A Radiologist or Registered Medical Practitioner for carrying out ultrasonography. The required experience shall be 100 cases under supervision of a similarly qualified person experienced in these techniques.

FORM A

[See rules 4(1) and 8(1)]
(To be submitted in Duplicate)

WITH SUPPORTING DOCUMENTS AS ENCLOSURES, ALSO IN DUPLICATE FORM OF APPLICATION FOR REGISTRATION OR RENEWAL OF REGISTRATION OF A GENETIC COUNSELLING CENTRE/GENETIC LABORATORY/GENETIC CLINIC

1.Name of the applicant

(specify Sh./Smt./Kur./Dr.)

2.Address of the applicant

3.Capacity in which applying

(specify owner/partner/managing director/other-to be stated)

4.Type of facility to be registered

(specify Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/any combination of these)

5.Full name and address/addresses of Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic with Telephone/Telegraphic Telex/Fax E-mail numbers.

6.Type of ownership and Organisation (specify individual ownership/partnership/company/co-operative/any other). In case of type of organization other than individual ownership, furnish copy of articles of association and names and addresses of other persons responsible for management, as enclosure.

7.Type of Institution (Govt. Hospital/Municipal Hospital/Public Hospital/Private Hospital/Private Nursing Home/Private Clinic/Private Laboratory/any other to be stated.) 8. Specific pre-natal diagnostic procedures/tests for which approval is sought (for example amniocentesis, chorionic villi aspiration/chromosomal/biochemical/molecular studies etc.)

Leave blank if registration sought for Genetic Counselling Centre only.

9.(a) Space available for the Counselling Centre/Clinic/Laboratory give total work area excluding lobbies, waiting rooms, stairs etc. and enclose plan)

10.Equipment available with the make and model of each equipment. List to be attached on a separate sheet.

11. (a) Facilities available in the Counselling Centre.

(b) Whether facilities are available in the Laboratory/Clinic for the following tests:

- (i) Ultrasound
- (ii) Amniocentesis
- (iii) Chorionic villi aspiration
- (iv) Foetoscopy
- (v) Foetal biopsy
- (vi) Cordocentesis

(a) (b) Whether facilities are available in the Laboratory, Clinic for the following:

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

12.Names, qualifications, experience and registration number of employees may be furnished as an enclosure (Refer Schedules I, II or III).

13.State whether the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic^{1[1]} qualifies for registration in terms of minimum requirements laid down in Schedule I, II and III and if not, reasons therefore.

14. For renewal applications only:

(a) Registration No.

(b) Date of issue and date of expiry of existing certificate of registration.

15. List of Enclosures:

Please attach a list of enclosures giving the supporting documents enclosed to this application.

Date:

Place

(.....)
Name and signature of applicant

^{1[1]} Strike out whichever is not applicable or not necessary. All enclosures are to be authenticated by signature of the applicant.

DECLARATION

I, Sh./Smt./Kum./Dr..... son/daughter/wife of aged
..... years resident of

..... hereby declare that I have read and understood the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994) and the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1995,

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

Date:

Place (.....)
Name and signature of applicant

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* by (Name and address of applicant) has been received by the Appropriate Authority On (date).

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

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

Date:

SEAL

ORIGINAL
DUPLICATE FOR DISPLAY

FORM B

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

CERTIFICATE OF REGISTRATION

(To be issued in duplicate)

1. 1. In exercise of the powers conferred under Section 19 (1) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994), the Appropriate Authority hereby grants registration to the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic* named below for purposes of carrying out Genetic Counselling/Pre-natal Diagnostic Procedures*/Pre-natal Diagnostic Tests as defined in the aforesaid Act for a period of five years ending on
2. 2. This registration is granted subject to the aforesaid Act and Rules thereunder and any contravention thereof shall result in suspension or cancellation of this Certificate of Registration before the expiry of the said period of five years.
 - A. Name and address of the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*.
 - B. Name of Applicant for registration.
 - C. Pre-natal diagnostic procedures approved for (Genetic Clinic).
 - (i) Ultrasound
 - (ii) Amniocentesis
 - (iii) Chorionic villi biopsy
 - (iv) Foetoscopy
 - (v) Foetal skin or organ biopsy
 - (vi) Cordocentesis
 - (vii) Any other (specify)
 - D. D. Pre-natal diagnostic tests* approved (for Genetic Laboratory)
 - (i) Chromosomal studies
 - (ii) Biochemical studies
 - (iii) Molecular studies
3. 3. Registration No. allotted
4. 4. For renewed Certificate of Registration only
Period of validity of earlier Certificate From To Or Registration.

**Signature, name and designation of
The Appropriate Authority**

Date:

SEAL

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)]

REJECTION OF APPLICATION FOR REGISTRATION OR RENEWAL OF REGISTRATION

In exercise of the powers conferred under Section 19(2) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994, the Appropriate Authority Hereby rejects the application for grant*/renewal* of registration of the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic* named below for the reasons stated.

Name and address of the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*

Name of Applicant who has applied for registration

Reasons for rejection of application for registration

Signature, name and designation of

The Appropriate Authority

Date:

SEAL

*Strike out whichever is not applicable or necessary.

FORM D
[See rule 9(2)]

**NAME, ADDRESS AND REGISTRATION No. OF GENETIC COUNSELLING CENTRE
RECORD TO BE MAINTAINED BY THE GENETIC COUNSELLING CENTRE**

1. Patient's name
2. Age
3. Husband's/Father's name
4. Full address with Tel. No., if any
5. Referred by (Full name and address of Doctor(s) with registration No.(s) (Referred note to be preserved carefully with case papers)
6. Last menstrual period/weeks of pregnancy
7. History of genetic/medical disease in the family (specify) Basis of diagnosis:
 - (a) Clinical
 - (b) Bio-chemical
 - (c) Cytogenetic
 - (d) Other (e.g.radiological)
8. 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) Any other (specify)
 - B. Advanced maternal age (35 years)
 - C. Mother/father/sibling has genetic disease (specify)
 - D. Others (specify)
9. Procedure advised^{2[2]}
 - (i) Ultrasound
 - (ii) Amniocentesis
 - (iii) Chorionic villi biopsy
 - (iv) Foetoscopy
 - (v) Foetal skin or organ biopsy
 - (vi) Cordocentesis
 - (vii) Any other (specify)
- 10.Laboratory tests to be carried out
 - (i) Chromosomal studies
 - (ii) Biochemical studies
 - (iii) Molecular studies
11. Result of pre-natal diagnosis
If abnormal give details. Normal/Abnormal
12. Was MTP advised?
13. Name and address of Genetic Clinic* to which patient referred.
14. Dates of commencement and completion of genetic counseling.

**Name, Signature and Registration No. of the
Medical Geneticist/Gynaecologist/Paediatrician**

Date:

^{2[2]} Strike out whichever is not applicable or necessary.

FORM E
[See Rule 9(3)]

**NAME, ADDRESS AND REGISTRATION No. OF GENETIC LABORATORY RECORD TO
BE MAINTAINED BY THE GENETIC LABORATORY**

1. Patient's name
2. Age
3. Husband's/Father's name
4. Full address with Tel. No., if any
5. Referred by/sample sent by (full name and address of Genetic Clinic) (Referral note to be preserved carefully with case papers)
6. Type of sample: Maternal blood/Chorionic villus sample/amniotic fluid/Foetal blood or other foetal tissue (specify)
7. 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) Any other (specify)
 - B. Advanced maternal age (>35 years)
 - C. Mother/father/sibling has genetic disease (specify)
 - D. Other (specify)
8. Laboratory tests carried out (give details)
 - (viii) Chromosomal studies
 - (ix) Biochemical studies
 - (x) Molecular studies
9. Result of pre-natal diagnosis
If abnormal give details. Normal/Abnormal
10. Date(s) on which tests carried out.
The results of the Pre-natal diagnostic tests were conveyed to on
.....

**Name, Signature and Registration No. of the
Medical Geneticist**

Date:

FORM F
[See Rule 9(4)]

**NAME, ADDRESS AND REGISTRATION No. OF GENETIC CLINIC
RECORD TO BE MAINTAINED BY THE GENETIC CLINIC**

1. Patient's name
2. Age
3. Husband's/Father's name
4. Full address with Tel. No., if any
5. Referred by (full name and address of Doctor(s)/Genetic Counselling Centre (Referral note to be preserved carefully with case papers)
6. Last menstrual period/weeks of pregnancy
7. History of genetic/medical disease in the family (specify) Basis of diagnosis:
 - (a) Clinical
 - (b) Bio-chemical
 - (c) Cytogenetic
 - (d) Other (e.g. radiological-specify)
8. 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) Any other (specify)
 - B. Advanced maternal age (35 years)
 - C. Mother/father/sibling has genetic disease (specify)
 - D. Other (specify)
9. Procedures carried out (with name and registration No. of Gynaecologist/Radiologist/Registered Medical Practitioner) who performed it.
 - (i) Ultrasound
 - (ii) Amniocentesis
 - (iii) Chorionic Villi aspiration
 - (iv) Foetal biopsy
 - (v) Cordocentesis
 - (vi) Any other (specify)
10. Any complication of procedure – please specify
11. Laboratory tests recommended^{3[3]}
 - (i) Chromosomal studies
 - (ii) Biochemical studies
 - (iii) Molecular studies
12. Result of pre-natal diagnostic procedure and specify Normal/Abnormal abnormality detected, if any.
13. Was MTP advised/conducted?
14. Date(s) on which procedures carried out.

^{3[3]} Strike out whichever is not applicable or not necessary.

15. Date on which MTP carried out.

16. Date on which consent obtained.

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

**Name, Signature and Registration number of the
Gynaecologist/Radiologist/Registered Medical
Practitioner**

**Date:
Place**

FORM G
[See Rule 10]
FORM OF CONSENT

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 pre-natal diagnostic procedures in my interest to find out the possibility of any abnormality (i.e. deformity or disorder) in the child I am carrying.

I undertake not to terminate the pregnancy if the pre-natal procedure and any pre-natal tests conducted show the absence of deformity or disorders. 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).

Date
Place

Signature

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

**Name, Signature and/Registration number
Of Gynaecologist**

Date

**Name, Address and Registration number of
Genetic Clinic**

FORM H
[See Rule 9(5)]

**PERMANENT RECORD OF APPLICATION FOR REGISTRATION, GRANT OF REGISTRATION
REJECTION OF APPLICATION FOR REGISTRATION AND RENEWALS OF REGISTRATION**

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*.
6. Date on which case considered by Advisory Committee and recommendation of Advisory Committee, in summary.
7. Outcome of application (state granted/rejected and date of issue of orders).
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) Against item 7, record date of issue of order in Form B or Form C.
- (d) On renewal, the Registration Number of the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic will not change. A fresh registration Number will be allotted in the event of change of ownership or management.
- (e) No registration number shall be allotted twice.
- (f) Each Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic may be allotted a folio consisting of two facing pages of the Register for recording Form H.
- (g) 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.
- (h) 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.

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

G.S.R. 540 (E), dated 26th November, 1996- In exercise of the powers conferred by Sec.32 of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994), the Central Government hereby makes the following rules, namely:-

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

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

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

3. Terms and conditions of appointment as a member of an Advisory Committee.- (1) No person shall be appointed as a member of an Advisory Committee if he –

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

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

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

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

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

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

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

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

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

4. Meetings of the Advisory Committees.- The intervening period between any two meetings of an Advisory Committee shall not exceed sixty days.

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

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

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

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

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

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

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

9. Assistance to be rendered by the Appropriate Authority to the Advisory Committee.- (1) Every meeting of the Advisory Committee shall be attended by the Appropriate Authority concerned.

(2)All secretarial and other assistance to the Advisory Committee for the discharge of its functions shall be provided by the Appropriate Authority.

(3)The Appropriate Authority shall issue the notice of meeting, agenda, notes on agenda and the minutes of the meeting, in consultation with the Chairman, subject to the provisions of Rules 5,6, 7 and 12.

10. Decisions on questions before the Advisory Committee.- (1) The advice tendered by the Advisory Committee shall be adopted, and in the event of any difference of opinion amongst the members, the matter shall be put to vote and decided by a simple majority of the members present.

(2)The Appropriate Authority shall not have a right to vote.

(3)In the event of tie in votes, the Chairman or in his absence, the member presiding shall have a second or casting vote.

(4)The fact of any question having been decided by the process of voting instead of by adoption, shall be recorded in the minutes of that meeting of the Advisory Committee.

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

(a) any vacancy in, or any defect in the constitution of the Advisory Committee; or

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

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

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

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EXTRAORDINARY
PART II – Section I

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NEW DELHI, MONDAY, JANUARY 20, 2003/ PAUSA

MINISTRY OF LAW AND JUSTICE
(Legislative Department)
New Delhi, the 20th January, 2003/Pausa 30, 1924 (Saka)

The following Act of Parliament received the assent of the President on the 17th January, 2003, and is hereby published for general information :-

THE PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) AMENDMENT ACT, 2002

No. 14 of 2003

[17th January, 2003]

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

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

- 1.(1) This Act may be called the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act, 2002. Short title and commencement
- (2) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.
- 57 of 1994 2. In the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (hereinafter referred to as the principal Act), for the long title, the following long title shall be substituted, namely:- Substitution of long title.
- "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."
- Amendment of section 1. 3. 3. In section 1 of the principal Act, in sub-section (1), for the words and brackets "the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse)", the words and brackets "the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection)" shall be substituted.
- Amendment of section 2. 4. In section 2 of the principal Act, -
- (i) after clause (b), the following clauses shall be inserted, namely:-

(ba) “conceptus” means any product of conception at any stage of development from 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;’;

(ii) in clause(d), the following *Explanation* shall be added, namely:-

‘*Explanation* – For the purpose of this clause, “Genetic Clinic” includes a vehicle, where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used;’;

(iii) in clause (e), the following *Explanation* shall be added, namely:-

‘*Explanation:-* For the purposes of this clause “Genetic Laboratory” includes a place where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection of sex during pregnancy or selection of sex before conception, is used;’;

(iv) for clause(g), the following clause shall be substituted, namely:-

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

102 of 1956

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

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

(v) for clause (i), the following clause shall be substituted, namely:-

‘(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;’;

(vi) for clause (k), the following clause shall be substituted, namely:-

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

(vii) after clause (n), the following clauses shall be inserted, namely:-

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

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

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

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

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

Amendment of section 3.

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

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

Insertion of new sections 3A and 3B.

“3A. 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.

Prohibition of sex-selection.

3B. 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 Councelling Centre, Genetic Laboratory, Genetic Clinic or any other person not registered under the Act.”.

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

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

Amendment of section 4.

“(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.”.

Amendment
of section 5.

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

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

Amendment
of section 6.

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

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

Amendment
of Section 7

10. In section 7 of the principal Act,-

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

“(c) three members to be appointed by the Central Government to represent the Ministeries of Central Government in charge of Women and Child Development, Department of Legal Affairs or Legislative Department in the Ministry of Law, Justice, and Indian System of Medicine and Homeopathy, ex officio;”;

(ii) in clause (e), for sub-clause (ii), the following sub-clause shall be substituted, namely:-

“(ii) eminent gynaecologist and obstetrician or expert of striroga or prasuti-tantra.”.

Amendment
of section 14.

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

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

Amendment
of section 15.

12. In section 15 of the principal Act, the following proviso shall be inserted, namely: -

“Provided that no member other than an ex-officio member shall be appointed for more than two consecutive terms.”.

Substitution of new section for section 16.

Functions of the Board.

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

“16. 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 take appropriate steps to ensure its proper and effective implementation;

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

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

Insertion of new section 16A.

“16A (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: -

Constitution of State Supervisory Board and Union territory Supervisory Board.

(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 Homeopathy, ex officio, or their representatives;

(d) Director of Health and Family Welfare or Indian System of Medicines and Homeopathy 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 organizations or otherwise;

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

(iv) eminent pediatricians or medical geneticists;

(v) eminent radiologists or sonologists;

(g) an officer not below the rank of Joint Director incharge of Family Welfare, who shall be the Member Secretary, ex officio

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

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

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

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

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

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

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

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

[Amendment of section 17.](#) 15. In section 17 of the principal Act,-

(i) in sub-section (3), for clause (a), the following clause shall be substituted, namely:-

“(a) when appointed for the whole of the State or the Union territory, consisting of the following three members -

(i) an officer of or above the rank of the Joint Director of Health and Family Welfare - Chairperson;

(ii) an eminent woman representing women’s 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.”;

(ii) in sub-section (4), after clause (d), the following clauses shall be inserted, namely:-

“(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.”;

(iii) for sub-section (7), the following sub-section shall be substituted, namely:-

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

16. After section 17 of the principal Act, the following section shall be inserted, namely :-

Insertion of new section 17A.

“17A. The Appropriate Authority shall have the powers in respect of the following matters, namely :-

Powers of Appropriate Authorities.

(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.”.

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

Amendment of section 18.

“(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.”.

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

Substitution of new section for section 22.

’22. (1) No person, organisation, Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, including clinic, laboratory or

Prohibition of

centre having ultrasound machine or imaging machine or scanner or any other technology capable of undertaking determination of sex of the foetus or sex selection shall issue, 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.

advertisement relating to pre-conception and pre-natal determination of sex and punishment for contravention.

(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."

Amendment of section 23.

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

“(2) The name of the registered medical practitioner shall be reported by the Appropriate Authority to the State Medical Council concerned for taking necessary action including suspension of the registration 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 women for the purposes other than those specified in sub-section (2) of section 4, he shall, be punishable with imprisonment for a term which may extend to three years and with fine which may extend to fifty thousand rupees for the first offence and for any subsequent offence with imprisonment which may extend to five years and with fine which may extend to one lakh rupees.

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

20. For section 24 of the principal Act, the following section shall be substituted, namely:-

Substitution of new section for section 24.

Presumption in the case of conduct of

“24 Notwithstanding anything contained in the Indian Evidence Act, 1872, the court shall presume unless the contrary is proved that the pregnant woman was compelled by her husband or any other

pre-natal
diagnostic
techniques.

relative, as the case may be, to undergo pre-natal diagnostic technique for the purposes other than those specified in sub-section (2) of section 4 and such person shall be liable for abetment of offence under sub-section (3) of section 23 and shall be punishable for the offence specified under that section.”.

21. In section 28 of the principal Act, in sub-section (1), in clause (b), for the words “thirty days”, the words “fifteen days” shall be substituted. [Amendment of section 28.](#)

22. In section 30 of the principal Act, for sub-section (1), the following sub-section shall be substituted, namely:- [Amendment of section 30.](#)

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

23. After section 31 of the principal Act, the following section shall be inserted, namely:- [Insertion of new section 31 A.](#)

“31A. (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:

[Removal of difficulties.](#)

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.”.

24. In section 32, in sub-section (2),- [Amendment of section 32.](#)

(i) for clause (i), the following clauses shall be substituted, namely:-

“(i) the minimum qualifications for persons employed at a registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic under clause (2) of section 3;

(ia) the manner in which the person conducting

ultrasonography on a pregnant woman shall keep record thereof in the Clinic under the proviso to sub-section (3) of section 4;”;

(ii) after clause (iv), the following clauses shall be inserted, namely:-

“(iva) code of conduct to be observed by persons working at Genetic Counselling Centres, Genetic Laboratories and 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;”.

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K.N. CHATURVEDI,
Additional Secy. To the Govt. of India

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New Delhi, FRIDAY, FEBRUARY 14, 2003 /MAGHA 25, 1924

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Family Welfare)
NOTIFICATION
New Delhi, the 14th February, 2003

**The Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse)
Amendment Rules, 2003.**

G.S.R.109(E).- 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 amendments to the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996.

1. (1) These may be called the **Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Rules, 2003.**

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

2. In the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996 (hereinafter referred to as the said rules) in rule 1, for sub-rule (1) the following sub-rule shall be substituted, namely:-

“(1) These Rules may be called the **Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996.**”

3. In the said rules, in rule 2, clause (d) shall be omitted.

4. In the said rules, for rule 3 the following rule shall be substituted, namely:-

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

(1) Any person being or employing

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

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

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

- (i) a Medical Geneticist and
- (ii) a laboratory technician, having a B.Sc. degree in Biological Sciences or a degree or diploma in medical

laboratory course with at least one year experience in conducting appropriate prenatal diagnostic techniques, tests or procedures may set up a genetic laboratory.

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

(i) Chromosomal studies:

- (1) Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.
- (2) Photo-microscope with fluorescent source of light.
- (3) Inverted microscope.
- (4) Incubator and oven.
- (5) Carbon dioxide incubator or closed system with 5% 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 Radio-immunoassay system (with gamma beta-counter) or fluorometer for various biochemical tests.
- (12) Vortex mixer.
- (13) Magnetic stirrer.
- (14) pH meter.
- (15) A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.
- (16) Double distillation apparatus (glass).
- (17) Liquid nitrogen tank.
- (18) Such other equipments as may be necessary.

(iii) Molecular studies:

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

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

- (a) Gynaecologist having experience of performing at least 20 procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis foetoscopy, foetal skin or organ biopsy or foetal blood sampling etc. under supervision of an experienced gynaecologist in these fields, or
- (b) a Sonologist, Imaging Specialist, Radiologist or Registered Medical Practitioner having Post Graduate degree or diploma or six months training or one year experience in sonography or image scanning, or.
- (c) A medical geneticist.

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

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

- (a) Equipment and accessories necessary for carrying out clinical examination by an obstetrician or gynaecologist.
- (b) An ultra-sonography machine including mobile ultrasound machine, imaging machine or any other equipment capable of conducting foetal ultrasonography.
- (c) Appropriate catheters and equipment for carrying out chorionic villi aspirations per vagina or per abdomen.
- (d) Appropriate sterile needles for amniocentesis or cordocentesis.
- (e) A suitable foetoscope with appropriate accessories for foetoscopy, foetal skin or organ biopsy or foetal blood sampling shall be optional.
- (f) Equipment for dry and wet sterilization.

- (g) Equipment for carrying out emergency procedures such as evacuation of uterus or resuscitation in case of need.
- (h) Genetic Works Station.”.

5. In the said rules, after rule 3 a new rule 3A shall be inserted as follows, namely:-

“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.”.

6. In the said rules, in rule 4 for sub-rule (1) the following sub-rule shall be substituted, namely:-

“(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.”.

7. In the said rules, for rule 5, the following rule shall be substituted, namely:-

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

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

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

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

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

8. In the said rules, in rule 9, -

(a) for sub-rule (1), the following sub-rule shall be substituted, namely:-

“(1) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres shall maintain a register showing, in serial order, the names and addresses of the men or women given genetic counselling, subjected to pre-natal diagnostic procedures or pre-natal diagnostic tests, the names of their spouse or father and the date on which they first reported for such counselling, procedure or test.”;

(b) for sub-rule (3), the following sub-rule shall be substituted, namely:-

“(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.”;

(c) for sub-rule (4), the following sub-rule shall be substituted, namely:-

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

(d) after sub-rule (7), the following sub-rule shall be inserted, namely:-

“(8) Every Genetic Counseling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres shall send a complete report in respect of all pre-conception or pregnancy related procedures/ techniques/tests conducted by them in respect of each month by 5th day of the following month to the concerned Appropriate Authority.”.

9. In the said rules, in rule 10, -

(a) for sub-rule (1), the following sub-rule shall be substituted, namely:-

“(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.”;

(b) after sub-rule (1), the following new sub-rule (1A) shall be inserted, namely:-

“(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.”.

10. In the said rules, for rule 11, the following rule shall be substituted, namely:-

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

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

11. In the said rules, in rule 12 for sub-rule (1), the following sub-rule shall be substituted, namely:-

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

Explanation:- In these Rules –

(1) ‘Genetic Laboratory/Genetic Clinic/ Genetic Counselling Centre’ would include an ultrasound centre/imaging centre/ nursing home/hospital/institute or any other place, by whatever name called, where any of the machines or equipments capable of selection of sex before or after conception or performing any procedure, technique or test for 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.”.

12. In the said rules, after rule 17, the following rules shall be inserted, namely:-

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

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

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

19. Appeals. –

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

13. In the said rules, Schedule I, Schedule II and Schedule III shall be omitted.

14. In the said rules, for the words “Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic”, the words “Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres” shall be substituted wherever they occur.

15. In the said rules, for Form A, Form B, Form C, Form D, Form E, Form F, Form G, and Form H, the following forms shall be substituted respectively, namely:-

“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 (i) 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

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

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

- (iii) Molecular studies
- (iv) 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^{4[1]} qualifies for registration in terms of requirements laid down in Rule 3]

12. For renewal applications only:
 (a) Registration No.
 (b) Date of issue and date of expiry of existing certificate of registration.

13. List of Enclosures:
 (Please attach a list of enclosures / supporting documents attached to this application.)

Date:

(.....)

Place

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

DECLARATION

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

(.....)

Place

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

[SEAL OF THE ORGANISATION SOUGHT TO BE REGISTERED]

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

^{4[1]} Strike out whichever is not applicable or not necessary. All enclosures are to be authenticated by signature of the applicant.

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

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

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

Date:
Place:

SEAL

ORIGINAL/DUPLICATE FOR DISPLAY

FORM B

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

CERTIFICATE OF REGISTRATION

(To be issued in duplicate)

5. 1. In exercise of the powers conferred under Section 19 (1) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994), the Appropriate Authority hereby grants registration to the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*/Ultrasound Clinic*/Imaging Centre* named below for purposes of carrying out Genetic Counselling/Pre-natal Diagnostic Procedures*/Pre-natal Diagnostic Tests/ultrasonography under the aforesaid Act for a period of five years ending on
6. 2. This registration is granted subject to the aforesaid Act and Rules thereunder and any contravention thereof shall result in suspension or cancellation of this Certificate of Registration before the expiry of the said period of five years apart from prosecution.
- A. Name and address of the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*/Ultrasound Clinic*/Imaging Centre*.
- B. Pre-natal diagnostic procedures* approved for (Genetic Clinic).
Non-Invasive
(i) Ultrasound
Invasive
(ii) Amniocentesis
(iii) Chorionic villi biopsy
(iv) Foetoscopy
(v) Foetal skin or organ biopsy
(vi) Cordocentesis
(vii) Any other (specify)
- C. Pre-natal diagnostic tests* approved (for Genetic Laboratory)
(i) Chromosomal studies
(ii) Biochemical studies
(iii) Molecular studies
- D. Any other purpose (please specify)
3. Model and make of equipments being used (any change is to be intimated to the Appropriate Authority under rule 13).
4. Registration No. allotted
5. Period of validity of earlier Certificate of Registration.
(For renewed Certificate of Registration only) From To

Signature, name and designation of
The Appropriate Authority

Date:

SEAL

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, the Appropriate Authority hereby 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:

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

Date:
Place:

*Strike out whichever is not applicable or necessary.

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. 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^{5[2]}
 - (i) Ultrasound
 - (ii) Amniocentesis
 - (iii) Chorionic villi biopsy
 - (iv) Foetoscopy

 - (v) Foetal skin or organ biopsy
 - (vi) Cordocentesis
 - (vii) Any other (specify)

^{5[2]} Strike out whichever is not applicable or necessary.

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 counseling.

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

Place:
Date:

FORM E
 [See Rule 9(3)]
FORM FOR MAINTENANCE OF RECORDS BY GENETIC LABORATORY

1. Name and address of Genetic 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

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

Place:
 Date:

FORM F

[See Proviso to Section 4(3), Rule 9(4) and Rule 10(1A)]
FORM FOR MAINTENANCE OF RECORD IN RESPECT OF PREGNANT WOMAN BY GENETIC
CLINIC/ULTRASOUND CLINIC/IMAGING CENTRE

1. Name and address of the Genetic Clinic/Ultrasound Clinic/Imaging Centre.
2. Registration No.
3. Patient's name and her age
4. Number of children with sex of each child
5. Husband's/Father's name
6. Full address with Tel. No., if any
7. Referred by (full name and address of Doctor(s)/Genetic Counselling Centre (Referral note to be preserved carefully with case papers)/self referral
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 etc. specify)
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)
 - C. Mother/father/sibling has genetic disease (specify)
 - D. Other (specify)
11. Procedures carried out (with name and registration No. of Gynaecologist/Radiologist/Registered Medical Practitioner) who performed it.

Non-Invasive

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

Invasive

- (ii) Amniocentesis
- (iii) Chorionic Villi aspiration
- (iv) Foetal biopsy
- (v) Cordocentesis
- (vi) Any other (specify)

12. Any complication of procedure – please specify

13. Laboratory tests recommended^{6[3]}

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

14. 14. Result of

(a) pre-natal diagnostic procedure
(give details)

(b) Ultrasonography

Normal/Abnormal

(specify abnormality detected, if any).

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

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

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

18. Was MTP advised/conducted?

19. Date on which MTP carried out.

Date:
Place

Name, Signature and Registration number of the
Gynaecologist/Radiologist/Director of the Clinic

DECLARATION OF PREGNANT WOMAN

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

Signature/Thump impression of pregnant woman

3 Strike out whichever is not applicable or not necessary

DECLARATON OF DOCTOR/PERSON CONDUCTING ULTRASONOGRAPHY/IMAGE SCANNING

I, _____ (name of the person conducting ultrasonography/image scanning) declare that while conducting ultrasonography/image scanning on Ms. _____ (name of the pregnant woman), I have neither detected nor disclosed the sex of her foetus to any body in any manner.

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

Important Note:

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

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

FORM G
[See Rule 10]
FORM OF CONSENT
(For invasive techniques)

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

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

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

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

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

Date
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

Date

Name, Address and Registration number of
Genetic Clinic/Institute

SEAL

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.SI. 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.
- (e) Registration number shall not be allotted twice.
- (f) 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.
- (g) 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.
- (h) 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.”.

(Ms. K. Sujatha Rao)

Joint Secretary to the Government of India.

[No.N.24026/14/2002-PNDT Cell]

Footnote:- The Principal Notification was published in the Gazette of India vide No.G.S.R. 1(E) dated 1st January, 1996. This is the first amendments to the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996.