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#### **NOTIFICATION**

No.Z.11013/6/96-PDT, the 28th April, 1998. The Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 and Diagnostic Techniques (Regulation and prevention of misuse) Rules, 1996 notified in Gazette of India on 20.9.94 and 1.1.96 respectively by Ministry of Health and Family Welfare, Govt. of India, New Delhi is republished in the Gazette of State Govt. for general information.

**T. Sangknnga,**  
Deputy Secretary to the Govt. of Mizoram,  
Health & Family Welfare Department.

**MINISTRY OF LAW, JUSTICE AND COMPANY AFFAIRS**

(Legislative Department)

New Delhi, the 20th September, 1994/Bhadra 29, 1916 (Saka)

The following Act of Parliament received the assent of the President on the 20th September 1994, and is hereby published for general information:—

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

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 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 therewith or incidental, thereto.

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

CHAPTER I

PRELIMINARY

1. (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.

**Short title,  
extent and  
commence-  
ment.**

Defini-  
tions.

2. 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 Counselling Centre ” means an institute, hospital, nursing home or any place, by whatever name called, which provides for genetic counselling to patients;

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

(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) " gynaecologist " means a person who possesses a post-graduate qualification in gynaecology 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; or 102 of 1956.

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

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

(i) " pre-natal diagnostic procedures " means all gynaecological or obstetrical or medical procedures such as ultrasonography foetoscopy, taking or removing samples of amniotic fluid, chorionic villi, blood or any tissues of a pregnant woman for being sent to a Genetic Laboratory or Genetic Clinic for conducting pre-natal diagnostic tests;

(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, and whose name has been entered in a State Medical Register; 102 of 1956.

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

## CHAPTER II

### REGULATION OF GENETIC COUNSELLING CENTRES, GENETIC LABORATORIES AND GENETIC CLINICS

3. 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.

Regulation  
of Genetic  
Counsel-  
ling Cen-  
tres, Gene-  
tic Labora-  
tories and  
Genetic  
Clinics.

## CHAPTER III

### REGULATION OF PRE-NATAL DIAGNOSTIC TECHNIQUES

4. 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;

Regulation  
of pre-  
natal diag-  
nostic  
techniques.

(v) 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).

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

5. (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 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.

Determi-  
nation of  
sex pro-  
hibited.

6. 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

Constitu-  
tion of  
Central  
Superviso-  
ry Board.

7. (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. (1) The term of office of a member, other than an ex-officio member, shall be,—

Term of  
office of  
member.

(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 sub-section, one year.

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

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

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

Meetings  
of the  
Board.

9. (1) The Board shall meet at such time and place, and shall observed 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) Any questions which come up before any meeting of the Board shall be decided by a majority of 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.

Vacancies  
etc. not to  
invalidate  
proceedings  
of the  
Board.

10. 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.

Tempo-  
rary asso-  
ciation of  
persons  
with the  
Board for  
particular  
purposes.

11. (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.



Appoint-  
ment or  
officers  
and  
other em-  
ployees of  
the Board.

12. (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. 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.

Authentica-  
tion of  
orders and  
other in-  
struments  
of the  
Board.

14. A person shall be disqualified for being appointed as a member if, he—

Disqualifi-  
cations for  
appoint-  
ment as  
member.

(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

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

Eligibility  
of member  
for re-  
appoint-  
ment Func-  
tions of  
the Board.

16. 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. (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.

Appro-  
priate Au-  
thority and  
Advisory  
Committees.

(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 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 organisation.

(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. (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.

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

(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 fee 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. (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.

Certificate  
of regis-  
tration.

(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.

Cancellation or suspension of registration.

20. (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 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 subsections (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 subsection (1).

#### Appeal.

21. 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

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

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

(2) No person 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 extend 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. (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.

Offences  
and pe-  
nalties.

(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 women (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.

1 of 1872. 24. Notwithstanding anything in the Indian Evidence Act, 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.

Presumption in the case of Conduct of Ante-natal diagnostic techniques.

25. 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.

Penalty for contravention of the provisions of the Act or rules for which to specific punishment is provided.

Offences by companies. 26. (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 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 knowledge or that he had exercised all due diligence to prevent to 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.

Offence to be cognizable, non-bailable and non-compoundable. 27. Every offence under this Act shall be cognizable non-bailable and non-compoundable.

Cognizance of offences. 28. (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 purposes of this clause, “person” includes a social organisation.

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

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

## CHAPTER VIII

### MISCELLANEOUS

29. (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: Maintenance of records.

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. (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.

Power to search and seize record, etc.

2 of 1974.

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

31. 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.

Protection of action taken in good faith.

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

Power to make rules.

(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 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.

Power to make regulations.

33. 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 there under to provide for—

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

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

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

Rules, and regulations to be laid before Parliament.

K.L. Mohanpuria,  
Secy. to the Govt. of India.

MINISTRY OF HEALTH AND FAMILY WELFARE  
NOTIFICATION

New Delhi, the 21st December, 1995.

S.O.990(E).—In exercise of the powers conferred by sub-section(3) of section 1 of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994), the Central Government hereby appoints the first day of January, 1996 as the date on which the said Act shall come into force.

[No.. N.23011/59/94-Ply]  
K.S. SUGATHAN, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE  
(Department of Family Welfare)

NOTIFICATION

New Delhi, the 1st January, 1996.

G.S.R. I(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 rules, namely:—

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 or registration shall be made to the Appropriate Authority, in duplicate, in Form A.

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

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 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 counselling 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 counselling, procedure or test.

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

(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 a permanent records.

(6) All case related-records, forms of consent, Laboratory results, microscopic pictures, sonographic plates or slides, recommendations and letters shall be preserved by the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic for a period of two years from the date of completion of counselling, pre-natal diagnostic procedure or pre-natal diagnostic test, as the case may be. In the event



of any legal proceedings, the records shall be preserved till the final disposal of legal proceedings, or till the expiry of the said period of two years, whichever is later.

(7) In case the Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic maintains records on computer or other electronic equipment, 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 obtained 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 authorised by the Appropriate Authority in this behalf.

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 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 authorised in this behalf and by the witnesses to the seizure.

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

(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:

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

32 (4) If any material object seized is perishable in nature, the Appropriate  
33 Authority, or the officer authorised in this behalf shall make arrangements prom-  
34 pably 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:

35 Provided that the refrigerator or other equipment used by the Genetic Coun-  
36 selling Centre, Genetic Laboratory or Genetic Clinic for preserving such perish-  
37 able 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, men-  
38 tion of keeping the material object seized, on the premises of the Genetic Coun-  
39 selling Centre or Genetic Laboratory or Genetic Clinic shall be made in the list  
40 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 arrange-  
ments, by way of mounting a guard or sealing of the premises of the Genetic  
43 Counselling Centre, Genetic Laboratory or Genetic Clinic, for safe keeping, listing  
44 and removal of documents, records, book or any other material object to be  
45 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  
47 Counselling Centre, Genetic Laboratory or Genetic Clinic shall intimate every  
48 change of employee, place, address and equipment installed, to the Appropriate  
49 Authority within a period of thirty days of such change.

50 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  
51 to it by a Genetic Clinic.

52 (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 moni-  
53 toring so as to prevent any damage to the foetus and placenta.

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

16. Allowances to members of the Central Supervisory Board.— (1) The  
ex-officio members, and other Central and State Government officers appointed  
to the Board will be entitled to Travelling Allowance and Daily Allowance for  
attending the meetings of the Board as per the Travelling Allowances rules appli-  
55 cable 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-officials 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 the effect that disclosure of the sex of the foetus is prohibited under law.

(2) At least one copy each of the Act and these rules shall be available on the premises of every Genetic Counselling Centre, Genetic Laboratory 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.

[No. 23011/59/94-PLY]

K.S. SUGATHAN, Jt. Secy.

#### SCHEDULE [See rule 3 (1)]

### REQUIREMENTS FOR REGISTRATION OF A GENETIC COUNSELLING CENTRE

#### A. PLACE

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

#### B. EQUIPMENT

Educational charts/models.

#### C. EMPLOYEES :

ANY ONE OF THE FOLLOWING :—

(1) Medical Geneticist.

(2) Gynaecologist with 6 months experience, in genetic counselling, or having completed 4 weeks' training in genetic counselling.

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

## 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 categorised separately for each of the undermentioned studies.

## CHROMOSOMAL STUDIES :

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

## Biochemical studies:

(requirements according to tests to be carried out).

- (1) Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.
- (2) Inverted microscope.
- (3) Incubator and oven.
- (4) Carbon dioxide incubator or closed system with 5% CO<sub>2</sub> atmosphere.
- (5) Autoclave.
- (6) Refrigerator.
- (7) Water bath.
- (8) Centrifuge.
- (9) Electrophoresis apparatus and power supply.
- (10) Chromatography chamber.
- (11) Spectro-photometer and Elisa reader or Radio-immunoassay system (with gamma beta counter) or fluorometer for various biochemical tests.

- (12) Vortex 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.

**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 (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.

**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 a septic arrangements.

**B. EQUIPMENT**

- (1) Equipment and accessories necessary for carrying out clinical examination by an obstetrician/gynaecologist.

- (2) Equipment, accessories, materials and 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.
- (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 as indicated at B above).
- (2) A Radiologist or Registered Medical Practitioner for carrying out ultrasonography. The required experience shall be 100 cases under supervision of a similarly qualified person experienced in these techniques.

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

### 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./Kum./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 organisation 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 Counseling 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

(c) 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 \* qualifies for registration in terms of minimum requirements laid down in Schedule I, II and III and if not, reasons therefor.
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.

## DECLARATION

I, Sh./Smt./Kumi./Dr. ....  
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.

(ii) I 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 :

Name and signature of applicant

Place :  
\_\_\_\_\_

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

Date :

Authority.

**SEAL**

\*Strike out whichever is not applicable or not necessary.  
 1 GI/96--4

**ORIGINAL**  
**DUPLICATE FOR DISPLAY**

**FORM B**

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

**CERTIFICATE OF REGISTRATION**

( To be issued in duplicate )

1. In exercise of the powers conferred under section 19(1) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994), the appropriate Authority .....  
 ..... hereby grants registration to the Genetic Counselling  
 • Centre\*/Genetic Laboratory\*/ Genetic Clinic\* 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. 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. Pre-natal diagnostic test\* approved (for Genetic Laboratory)
  - (i) Chromosomal studies
  - (ii) Biochemical studies
  - (iii) Molecular studies
- 3. Registration No. allotted
- 4. For renewed Certificate of Registration only

Period of validity of earlier Certificate From .....  
 ..... To ..... of Registration.

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

Date :

SEAL

\* Strike out whichever is not applicable or necessary.

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

## FORM C

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

REJECTION OF APPLICATION FOR REGISTRATION OR  
RENEWAL OF REGISTRATON

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 registration.

Signature, name and designation of  
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  
OUNSELLING 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) (Referral not 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) Cyto-genetic
- (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 ( $\geq 35$  years)

## C. Mother/father/sibling has genetic disease (specify)

## D. Others (specify)

## 9. Procedure advised\*

- (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 counselling.

Name, Signature and Regis-  
tration No. of the Medical  
Geneticist/Gynaecologist/  
Paediatrician.

Date :

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\*Strike out whichever is not applicable or not 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 paper).
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)
  - (i) Chromosomal studies
  - (ii) Biochemical studies
  - (iii) Molecular studies
9. Result of pre-natal diagnosis: if abnormal, give details
10. Date(s) on which tests carried out  
The result of the pre-natal diagnostic tests were conveyed to ..... on .....

Normal/Abnormal

Date :

Name, signature and Registration number of the Medical Geneticist.

## 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 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) Cyto-genetic
- (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 disorder
- (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\*

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

12. Result of pre-natal diagnostic procedure and specify abnormality detected, if any. Normal/Abnormal
13. Was MTP advised/conducted
14. Date(s) on which procedures carried out
15. Date on which MTP carried out
16. Date on which consent obtained.
17. The result of pre-natal diagnostic procedure were conveyed to.....  
 .....  
 .....on.....

Date :

Place :

Name, Signature and Registration Number  
 of the Gynaecologist/Radiologist/Regis-  
 tered Medical Practitioner

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

FORM G  
 [See rule 10]  
 FORM OF CONCENT

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 :

Signature

Place :

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

Date :

Name, Signature and registration num-  
 ber of Gynaecologist

Name, address and Registration num-  
 ber 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 Appropriation 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. Renewal, (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 whether 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.