

MINISTRY OF LAW JUSTICE AND COMPANY AFFAIRS

(Legislative Department)

New Delhi, the 20 th 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

[20 th 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 malformation 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 1

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.

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 Counseling Centre" Means an institute, hospital, nursing home or any place, by whatever name called, which provides for genetic counseling to patients;
- (d) "Genetic Clinic" means a clinic, institute, hospital, nursing home, or any place, by whatever name called, which is used for conducting pre-natal diagnostic procedures;
- (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 obstetries;
- (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 recognized under the Indian Medical Council Act, 1956; or
 - (ii) a post-graduate degree in biological sciences;

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

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

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

(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 geneaic or metabolic disorders or chromosomal abnormalities or congenital anomalies or haemoglobinopathies or sex-linked diseases;

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

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

(h) of section 2 of the Indian Medical Council Act, 1996 and whose name has been entered in a State Medical Register;

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

CHAPTER II

REGULATION OF COUNSELING CENTER GENETIC LABORATORIES AND GENETIC CLINICS

3. On and from the commencement of this Act,-

(1) No Genetic Counseling Center, Genetic Laboratory or Genetic Clinic unless registered under this Act, shall conduct or associate with, or help in conducting activities relating to prenatal diagnostic techniques;

(2) No Genetic Counseling Center, Genetic Laboratory or Genetic Clinic shall employed any person WHO does not possess the prescribed qualifications;

(3) No medical geneticist, gynecologist pediatrician registered medical practitioner or any other person shall conduct or cause to be conducted or aid in conducting by himself or through any person, any prenatal diagnostic techniques at a place other than a place registered under this Act.

CHAPTER III

REGULATION OF PRENATAL DIAGNOSTIC TECHNIQUES

4 On and from the commencement of this Act, -

(1) No place including a registered Genetic Counseling Center or genetic Laboratory or genetic Clinic shall be used or caused to be used by any person for conducting prenatal diagnostic techniques except for the purposes specified in clause (2) and after satisfying any of the conditions specified in clause (3)

(2) No prenatal 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)
- (vi) Any other abnormalities or diseases as may be specified by the Central Supervisory Board;

(3) No prenatal 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 fatal loss;
- (iii) the pregnant woman had been exposed to potentially Teratogenic agents such as drugs, radiation, infections or chemicals;

- (iv) the pregnant woman has a family history of mental retardation or physical deformities such as spastically 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 expect for the purpose specified in clause (2)

(5) (1) No person referred to in clause (w) of section 3 shall conduct the prenatal 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 fetus by words, signs or in any other manner.

(6) On and from the commencement of this Act.-

- (a) No genetic Counseling Center or Genetic Laboratory or Genetic Clinic shall conduct or cause to be conducted any prenatal diagnostic techniques including ultrasonography for the purpose of determining the sex of a fetus.
- (b) No person shall conduct or cause to be conducted any prenatal diagnostic techniques including ultrasonography for the purpose of determining the sex of a fetus.

CHAPTER IV

CENTRAL SUPERVISORY 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 function 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 law and Justice, ex-officio.
- (d) the Director 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 gynecologists and obstetricians;
 - (iii) eminent pediatrician;
 - (iv) eminent social scientists; and
 - (v) representatives of woman welfare organizations;
- (f) three woman of Parliament of whom two shall be elected by the House of the People and one by the Council of State;
- (g) four members to be appointed by the Central Government by rotation to represent the State and 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,-

(a) in case of appointment under clause (e) or clause (f) of subsection (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 function 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 function as may be assigned to him by the Chairman from time to time.

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

9. (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 meeting) as may be provided by regulations;

(2) The Chairman and in his absence the Vice Chairman shall preside at the meeting 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 members chosen by the member present at the meeting shall preside at the meeting.

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

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

10.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 the 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. (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 subsection (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. (1) For the purpose of enabling it efficiently to discharge, its functions under this Act., The Board may, subject to such regulation as may be made in this behalf, appoint (whether on deputation or other wise) 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 regulation.

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

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

- (a) has been convicted and sentenced to imprisonment for an offense 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 function as a member; or
- (f) has in the opinion of the Central Government been associated with the use or promotion of prenatal diagnostic techniques 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 reappointment as such member.

16. The Board shall have the following function, namely: -

- (i) to advise the Government on policy matters relating to use of prenatal diagnostic techniques;
- (ii) to review implementation of the Act and the rules made there under and recommend changes in the said Act and rules to the Central Government;
- (iii) to create public awareness against the practice of prenatal determination of sex and female foeticide;
- (iv) to lay down code of conduct to be observed by persons working at Genetic Counseling Center, Genetic Laboratories and Genetic Clinics;
- (vi) 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.

(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 prenatal sex determination leading to female foeticide.

(3) The officers appointed as Appropriate Authorities under subsection (1) or subsection (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 Authorities shall have the following functions:

(a) to grant, suspend or cancel registration of a Genetic Counseling Center Genetic Laboratory of Genetic clinic:

(b) to enforce standards prescribed for the Genetic Counseling Center Genetic Laboratory and Genetic clinic:

(c) to investigate complaints of breach of the Advisory Committee, constituted under subsection (5), on application for registration and on complaints for suspension or cancellation of registration.

CHAPTER VI

REGISTRATION OF GENETIC COUNSELING CENTER, GENETIC

LABORATORIES AND GENETIC CLINIC

(18) (1) No person shall open any Genetic Counseling Center Genetic Laboratory or Genetic Clinic after the commencement of this Act unless such Center, Laboratory or Clinic is duly registerec separately or jointly under this Act.

(2) Every application for registration under subsection (1), shall be made to the Appropriate Authorities in such form and in such manner and shall be accompanied by such fees as may be prescribed.

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

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

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

19.(1) The Appropriate Authorities shall after holding an inquiry and after satisfying itself that the applicant has compliec with all the requirements of this Act and the rules made there under and having regard to the advice of the advisory Committee in this behalf, grant a certificatior in the prescribed form jointly or separately to the Genetic Counseling Center 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 Authorities is satisfied that the applicant has not complied with the requirement of this Act or the rules, it shall, for reasons to be recorded in writing, reject the application for registration.

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CHAPTER VII

OFFENSE AND PENALTIES

- 22.(1) No person or organization, Genetic Counseling Center Genetic Laboratory or Genetic Clinic shall issue or cause to be issued any advertisement in any manner regarding facilities of prenatal determination of sex available at such Center, Laboratory or Clinic or any other place.
- (2) No person or organization shall publish or distribute or cause to be published or distributed any advertisement in any manner regarding facilities of prenatal determination of sex available at any Genetic Counseling Center Genetic Laboratory or Genetic Clinic or any other place.
- (3) Any person WHO contravenes the provisions of subsection (1) or subsection (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 by means of any light, sound, smoke or gas.

- 23.(1) Any medical geneticist, gynecologist, registered medical practitioner or any person who owns a Genetic Counseling Center Genetic Laboratory or Genetic Clinic or is employed in such a Center, Laboratory or Clinic and render his professional or technical services to or at such a Center, 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 connected by court under subsection (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 offense and permanently for the subsequent offense.

(3) Any person WHO seeks the aid of a Genetic Counseling Center Genetic Laboratory or Genetic Clinic or of a medical geneticist, gynecologist or registered medical practitioner for conducting prenatal 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 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 prenatal diagnostic technique and such person shall be liable for abatement of offenses under subsection (3) of section 23 and shall be punishable for the offense specified under that section.
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 of which may extend to three months or 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. (1) Where any offense, punishable under this Act has been committed by a company, every person who, at the time the offense 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 offense and shall be liable to be proceeded against and punished accordingly.

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

(2) Notwithstanding anything contained in subsection (1) where any offense punishable under this Act has been committed by a company and it is proved that the offense 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 shall also be deemed to be guilty of that offense and shall be liable to be proceeded against and punished accordingly.

Explanation.- For the purposes of this section.-

(a) "company" managed body corporate and includes a firm or other association of individual and

(b) "director" in relation to a firm means a partner in the firm.

27. Every offense under this Act shall be cognizable , non-bailable and non-compoundable.

28. (1) No court shall take cognizance of an offense under this Act except on a complaint made by –

(a) the Appropriate Authority concerned or any officer authorized in this behalf by the Central Government or State Government, as the case may be, or the Appropriate Authority or

(b) a person who has given motion of not less than thirty days in the manner prescribed to the Appropriate Authority of the alleged offense and of his mention to make a complaint to the court.

Explanation. – For the purpose of this clause "person includes a social organization.

(2) No court other than that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall by any offense 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 person

CHAPTER

MISCELLANEOUS

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

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

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

(30)(1) If the Appropriate Authority has reason to believe that an officer under this Act has been or is being committed at any Genetic Counseling Center Genetic Laboratory or Genetic Clinic such Authority or any officer authorized there of on this behalf may subject to such 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 Counseling Center Genetic Laboratory or Genetic Clinic and examine any record register book pamphlet advertisement or any other material object found therein and seize the same if may furnish evidence of the commission of an offense punishable under this Act.

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

(31) No suit, prosecution or other legal proceeding shall lie against officer authorized by the Center or the State Government or the Appropriate Authority or any officer authorized by the center 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)(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 person employed at a registered Genetic Counseling Center 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 center Supervisory Board in the discharge of their functions under subsection (4) of section 8;

(iv) allowances for members other than ex official members admissible under sub-section9;

(v) the period intervening between any two meeting of the appointed committee under the proviso to subsection (9) of section 17;

(vi) the form and manner in which an application shall be made for registration and the fee payable thereof under subsection (2) of section 18;

(vii) the form in which a certificate of registration shall be issued under subsection (1) of section 19;

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

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

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

(XI) 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 were or objects were seized under subsection (1) of section 30;

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

(33) The Board may with the previous sanction of the Central Government, by notification in the Official Gazette make regulation 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 meeting and the number of members which shall form the quorum under subsection (1) of section 9;

(b) the manner in which a person may be temporarily associated with the Board under subsection (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 Houses of Parliament, while it is an 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 expert of the session immediately following the session or the successive sessions aforesaid, both House agree in making any modification in the rule or regulation or both House agree that the rule or regulation should not be made, the rule or regulation have effect only in such modified or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation.

K.L. KOHANPURIA

Secy. To Govt. of India

MINISTRY OF HEALTH AND FAMILY

WELFARE

(Department of Family Welfare)

NOTIFICATION

New Delhi, the 1st January, 1996

G.S.R. 1(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.

3. definitions. In these rules, unless the context otherwise requires,-

(a) "Act" means The Prenatal Diagnostic Techniques (Regulation and Preventior of Misuse) Act, 1994 (57 of 1994);

(b) "employee" means a person working in or employed by a Genetic Counseling Center, 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;

4. Minimum requirements. - (1) The minimum qualifications of the employees, the minimum equipment and minimum place for a Genetic Counseling Center 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 Counseling Center Genetic Laboratory and Genetic Clinic, or any combination of these, it shall confirm to the requirements as specified in Schedules I, II, III.

5. Registration of Genetic Counseling Center Genetic Laboratory and Genetic Clinic.—(1) An application of registration shall, be made to Appropriate Authority in Form A.

(2) The Appropriate Authority or any person in his office authorized in this behalf, shall acknowledge receipt or the application Form registration, in the acknowledgment 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.

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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) Gynecologist with 6 months experience, in genetic counseling, or having completed 4 weeks training in genetic counseling.

(3) Pediatrician 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 our tests.

B. EQUIPMENT

These are categorized 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 or oven
- (5) Carbon dioxide incubator or closed system with 5% CO₂ atmosphere
- (6) Autoclave
- (7) Refrigerator
- (8) Water bath
- (9) Centrifuge
- (10) Vorted mixer
- (11) Magnetic stirrer
- (12) pH meter
- (13) A sensitive balance (preferable electronic) with sensitivity of 0.1 miligram
- (14) Double distillation apparatus(glass)

Biochemical studies :

(requirements according to tests to be carried out)

- (1) Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.
- (2) Inverted microscope
- (3) Incubator and oven
- (4) Carbon dioxide incubator or closed system with 5% CO₂ atmosphere
- (5) Autoclave
- (6) Refrigerator
- (7) Water bath

- (8) Centrifuge
- (9) Electrophoresis apparatus and power supply
- (10) Chromatography chamber
- (11) Spectro-photometer and Elisa reader or Radio-immunoassay system (with gamma beta-counter) or fluorometer for various biochemical tests.
- (12) Vortex 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) Vortexed 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 Science or a degree or a diploma in medical laboratory course with at least one year's experience in conducting appropriate pre-natal diagnostic tests.

SCHEDULE III

[See rule 3(1)]

REQUIREMENTS FOR REGISTRATION OF A

GENETIC CLINIC

A. PLACE

A room with an area of twenty (10) square metres with appropriate aseptic arrangements.

B. EQUIPMENT

- (1) Equipment, accessories necessary for carrying out clinical examination by an obstetrician/gynaecologist.
- (2) Equipment, accessories, material 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 carryi8ng 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

The required experience shall be 100 cases under supervision of a similarly qualified person experienced in these techniques.

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

FORM A

FORM B

FORM C

FORM D

FORM E

FORM F

FORM G

FORM H