

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

—33004/95 NO. D.L--S3W4/5 Che Gazette of •tidia 11 EXTRAORDINARY PART (I) PUBLISHED BY AUTHORITY 1, 11, NEW MONDAY, JANU.â.RY 1, 1996/PAUSA 11, qfQT(ftvr«r) 1996 g 994 (1994 57) 32 f«TQT) fâqq, 1996 (fi) "\$tfE•fiqxr" 1994 57) 11 GI 196 qqquif, (2) qP«uf (1) THE GAZETTE OF INDIA . EXTRAORDINARY [PART 11—SEC. 3(i)] 3iTT I fr47Tr Tazi 5. (4) mfgt- fig (\$) 2000. ooqqq 3000. oo (T) 30 00. 00 t, 4000. OO I 6. 1) Riflmer, qfiTfr VT a-a: ft.-q-t "T" ft'fhftz RTfi (6) OTT I qq- fig füt I tfrTücz 11-F% 3(i)] Q-ff qtr. , för Oaf't I q-QTfui, qqT 1*" it fqfnficz i? 3 xar q' (6) Cara, qfaxfRi I 10. 1) frTfiT I fi-,h f-fiü 142. 1) 4 THE GAZETTE OF NDIA : EXTRAORDINARY (PART 11—SEC. 30 gfä#m fStT crfimv•r arqr I Ffi, Q*z, faffi fqg qr qt qut qæg fig f*fr qxmi 13. qrrqTi 14. fizrTQ— Qtrr 15. 17 (5) äzG 'F«äf 16. * : fig 17. FT : (1) fq#g fig "t fT1 q«ttr qfQ?B7 5 qf#qbi ftQt ffr-•qT W. 2301 1159194--cft.v3. 1) (2) (3) 0) (2) (4) (5) (7) (8) fQS5, 6 4 Nfä& qzqrq QT I 6 (9) (10) (11) (1.3) (14) (1) (2) (3) (4) (5) (7) (8) (9) (10) (11) (12) (13) (14) (15) (16) (17) (1) (3) (4) (5) (6) (7) (9) 10) GAZETTE OF INDIA : EXTRAORDINARY -a-fü fä @ffitt) [PART 11—SEC. 3(i)] (2) (4 fsut 20 fifi QTfr 3(i)] 7 (11) 4) (16) (17) (i tfr. ft (qffirr) (20) I Xfif (4) Rf%zrT (1) üi' 5tfæT, 20 ffit fff 100 I Tffir 8 THE GAZETTE OF EXTRAORDINARY (1) fqzrq 80) ll—sgc. 30)) 5 qf«qf {TTT (q•Wf 11-qm 3(i)] 10. 11.) (37) 6. 12. MR, 13, 15. 9 1 G'f/96 2 10 THE GAZETTE OF INDIA EXTRAORDINARY fittPTT [PART 11—SEC. 3(Dl (f-afrr•qFT 1 994 57) frATRUT) fr17FT, 1995 (ii) ft-wit (a-r«i-q) fä-q•frffirr If-ac 3(i)] (3(2), 0(5) 2) (iT 'Äf-oii 11 1. f«rFt (fqfrrq7 3fiT. f«rq0T) 1994 (1992 57) ÄtiT*t ii qfxqrfrtr 2, 2 für für Gi-t-c 1. 2, 3. 6, fifä 3fTZ 12 2, 3. 4. 5. 6

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2. Definitions.In these rules, unless the context otherwise requires,— (a) "Act" means The Pre-natal Diagnostic niques (Regulation and Prevention of Mis- use) Act, 1994 (57 of 1994); (b) "employee" means a person working in or (c) (d) (e) (f) employed by a Genetic Counselling Centre. a Genetic Laboratory or a Genetic Clinic. and includes those working on part-lime. contractual, consultancy, honorary or on any other basis ; "Form" means a Form appended to these rules: "Schedule" means a Schedule appended to these rules ; "section" means a section of the Act ; words and expressions used herein and not defined in these rules but defined in the Act, shall have the meanings, respectively, assig- ned to them in the Act

3. Minimum requirements.—(1) The minimum qualifications of tho employees, the minimum equipment and minimum place for a Genetic Coun- selling Centre, Genetic Laboratory and Genetic. Clinic shall be as specified in Schcdules T, 11 and Ill. (2) Where an institute, hospital, nursing home. or any place, hy whatever name called, provides services jointly of Genetic Counselling Centre, (inetic Laboratory and Genetic Clinic, or any combination of these, it shall conform to the requirements os specified in Schedules I, 11 and Ill

4. Registration of Genetic Counselling Centre.Genetic Laboratory and Genetic An application or registration shall b:: made to lhe Appro- priate Authority, in duplicate, in Form A. (2) The Appropriate Authority, or any pcrcsn In his Office authoris«d in this behalf. shall acknowledge receipt oi 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 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 The Appropriate Authority shall, after making such enquiry and after satisfying itself that the applicant has complied with 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 or 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 iu Form B, for further period of five years from the drate of expiry of the certificate of registration earlier granted. (3) If, after enquiry and after giving an oppor- tunity 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 certi- ficate of registration and communicate such rejec- tion 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 subrule (1) of rule 19. (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 record.— (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 as permanent records. (6) All case related records, forms of consent, laboratory results, microscopic pictures, sonographic plates or slides, recommendations and letters shall be preserved by the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic for a period of two years from the date of completion of 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 facsimile, dot-matrix or other electronic equipment, 20 THE GAZETTE OF INDIA : EXTRAORDINARY [PART IV—sec. 3(i)] a printed copy of the record shall be taken and preserved after authentication by a person responsible for such record. 10. Conditions for conducting pre-natal diagnostic procedures. (1) Before conducting any pre-natal diagnostic procedure, a written consent, as specified in Form G, in a language the pregnant woman understands, shall be 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 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 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: Provided that a copy of the list of such document, record, register, book, pamphlet, advertisement or other material object seized may be delivered under acknowledgement, or sent by registered post to the owner or manager of the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, if no person acknowledging custody of the document, record, register, book, pamphlet, advertisement or other material object seized is available at the place of effecting the seizure. (4) If any material object seized is perishable in nature, the Appropriate Authority, or the officer authorised in this behalf shall make arrangements promptly for sealing, identification and preservation of the material object and also convey it to a facility for analysis or test, if analysis or test be required: Provided that the refrigerator or other equipment used by the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic for preserving such perishable material object may be sealed until such time as arrangements can be made for safe removal of such perishable material object and in such eventuality, mention of keeping the material object seized, on the premises of the Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic shall be made in the list of seizure. (5) In the case of non-completion of search and seizure operation, the Appropriate Authority or the officer authorised in this behalf may make arrangements, by way of mounting a guard or sealing of the premises of the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, for safe keeping, listing and

removal of documents, records, book or any other material object to be seized, and to prevent any tampering with such documents, records, books or any other material object. 13, Intimation of changes in employees, place or equipment.—Every Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall intimate every change of employee, place, address and equipment installed, to the Appropriate Authority within a period of thirty days of such change

14. Conditions for analysis or test and pre-natal (I) No Genetic Laboratory diagnostic procedures. shall accept for analysis or test any sample, unless referred to it by a Genetic Clinic. (2) Every pre-natal diagnostic procedure shall invariably be immediately preceded by locating the foetus and placenta through ultrasonography, and the pre-natal diagnostic procedure shall be done under direct ultrasonographic monitoring so as to prevent any damage to the foetus and placenta

15. Meetings of the Advisory Committees.—The intervening period any two meetings of Advisory Committees constituted under (5) of section 17 to advise the appropriate Authority shall not exceed sixty days. 16, Allowances to members of the Central Advisory Board. (1) The ex-officio members, and other Central and State Government officers appointed to it will be entitled to Travelling Allowance and Daily Allowance for attending the meetings or the Board as per the Travelling Allowance rules applicable to them. (2) The non-official members appointed to, and Members of Parliament elected to, the Board will be entitled to Travelling Allowance and Daily Allowance for attending the meetings of the Board as admissible to non-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 Centre 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 K. S. SUGATHAN, Jt. secy. SCHEDULE 11 [See rule 3 (1) I 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 11 [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) with fluorescent light. (3) (4) (5) (6) (7) (8) (9) THE GAZETTE OF INDIA : EXTRAORDINARY inverted microscope. Incubator and oven Carbon dioxide incubator or closed system with 5% CO₂ atmosphere. Autoclave. Refrigerator. Water bath. Centrifuge. [PART 11—SEC. (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) (4) (5) (6) (7) (8) (9) (10) (11) (12) (13) (14) (15) (16) (17) Incubator and oven Carbon dioxide incubator or closed system with 5% CO₂ atmosphere. Autoclave, Refrigerator. Water bath Centrifuge. Electrophoresis apparatus and power supply. Chromatography chart. Spectrophotometer and Elisa reader or Radio-immunoassay system (with gamma counter) or fluorometer for various biochemical tests. Vortex mixer. Magnetic stirrer. pH meter. A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram. Double distillation apparatus (glass). Liquid nitrogen tank. studies Inverted microscope. (1) Incubator. (2) (3) oven Autoclave. (4) Refrigerators (4 degree and minus 20 degree Centigrade) (5) Water bath. (6) Microcentrifuge. (7) Electrophoresis apparatus and power supply. (8) Vortex mixer. (9) Magnetic stirrer. (10) pH meter. (11) A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.

(12) Double distillation apparatus (glass) (13. P.C.R. machine. (14) Refrigerated centrifuge. (15) U.V. Illuminator with photographic attachment or other documentation system. (16) Precision micropipettes. (17) 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 prenatal diagnostic tests * 11-4< 3(i)l A. PLACE 23 SCHEDULE 111 iSee rule REQUIREMENTS FOR REGISTRATION OF A GENETIC CLINIC A room with an area of twenty (20) square metres with appropriate aseptic arrangements. B. EQUIPMENT (1) Equipment and accessories necessary for carrying out clinical examination by an obstetrician/gynaecologist. (2) Equipment, accessories, 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. *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 Telx(Fax E-mail numbers. [PART , 6. 7. 8. 9. 10. 11. 12. 13. 14. 15. 'ræ GAZETTE OF INDIA:- EXTRAORDINARY 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. Type of Institution (Govt. Hospital/Municipal Hospital/ Public Hospital/Private Hospital/Private Nursing Home/ Private Clinic/Private Laboratory/any other to be stated. Specific prenatal diagnostic procedures/tests for which approval is sought (for example amniocentesis, chorionic villi aspiration/chromosomal/biochemical/molecular studies etc). Leave blank if registration sought for Genetic Counselling Centre only (a) Space available for the Counselling Centre/Clinic/Laboratory give total work area excluding lobbies, waiting rooms, stairs etc. and enclose plan) Equipment available with the make and model of each equipment. List to be attached on a separate sheet). (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 Names, qualifications, experience and registration number of employees. May be furnished as an enclosure. (Refer Schedules I, II or III) 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 thereof* For renewal applications only. (a) Registration No. (b) Date of issue and date of expiry of existing certificate of registration. List of Enclosures : Please attach a list of enclosures giving the supporting documents enclosed to this application. Name and signature of applicant Date : Place. [MT II-Qta 3(i)] 1. Sh./Smt./Kum./Dr.. daughter/wife of.. 23 DECLARATION, resident Of. hereby declare that I 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, (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 declare that Act and rule- 3 fully complied with Name and signature of applicant Date : 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 80 The application in Form A in d.npl;catd for of registration of Genetic Counselling Centre/Genetic Laboratory*/Genetic Clinic by . . . (Name and address of applicant) has been received by the Appropriate Authority (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 Appropriate Authority, or authorized person in the office of the Appropriate Authority. Date : SEAL *Strike out whichever is not applicable or not necessary. I GI /96—4 26 THE GAZETTE OF INDIA,, EXTRAORDINARY [PART 11—sec, 301 ORIGINAL* DUPLICATE FOR DISPLAY FORM B [See rules 6(2), 6(5) and 8(2) CERTIFICATE OF REGISTRATION (To be issued in duplicate) I . In exercise of the powers under section 19(1) of the Prenatal 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*/ Prenatal Procedures*/Prenatal 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. Prenatal 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. Prenatal diagnostic tests* 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, . Registration. Date : Signature , name and designation of the Appropriate Authority..... , SEAL *Strike out whichever is not applicable or necessary. DISPLAY ONE COPY OF THIS CERTIFICATE AT A CONSPICUOUS PLACE AT THE PLACE BUSINESS. OF



FORM C [See rules 6(3), 6(5) and 8(3)] REJECTION OF APPLICATION FOR REGISTRATION OR RENEWAL OF REGISTRATION In exercise of the powers conferred under section 19(2) of the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 the Appropriate Authority....

.....he 'by rejects the application for registration of the Genetic Counselling Centre (to be named below for the reasons stated. Name and address of the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic* Name of Applicant who has applied for registration Reasons for rejection of application for registration Signature, name and designation of Appropriate Authority., Date SEAL *Strike out whichever is not applicable or necessary. 1. 3. 4. 5. 6. 7. 8.

FORM D (See rule 9(2)) NAME ADDRESS AND REGISTRATION. NO. OF GENETIC COUNSELLING CENTRE RECORD TO BE MAINTAINED BY THE GENETIC COUNSELLING CENTRE Patient's name Husband's, /Father's name Full address with Tel. NO. if any Referred by (Full name and address of Doctor(s) with registration No(s) (Referral note to be preserved carefully with case papers) Last menstrual period/.....,.....weeks of pregnancy 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) Indication for prenatal diagnosis* A. Previous child/children with: (i) Chromosomal disorders (ii) Metabolic disorders (iii) Congenital anomaly 28 THE GAZETTE OF INDIA :

EXTRAORDINARY [PART II—SEC. 3(i)] (iv) Mental retardation (v) Haemoglobinopathy (vi) Sex linked disorders (vii) Any other (specify) B. Advanced maternal age (—35 years) C. Mother/father/sibling has genetic disease (specify) D. Others (specify) 9. Procedure advised* (1) Ultrasound (ii) Amniocentesis (iii) Chorionic Villi biopsy (iv) Foetoscopy (v) Fetal 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 prenatal diagnosis : If abnormal give details. 12. Was MTP advised? 13. Name and address of Genetic Clinic* to which patient referred, 14. Dates of commencement and of genetic counselling. Date *Strike out whichever is not applicable or not necessary. Normal/Abnormal Name, Signature and Registration No. of the Medical Geneticist/Gynaecologist/ Paediatrician 1. 3. 4. 5

6. Form E [See rule 9 NAME, ADDRESS AND REGISTRATION NO. OF GENETIC LABORATORY RECORD TO BE MAINTAINED BY THE GENETIC LABORATORY Patient's name Husband's /Father's name Full address with Tel. No., if any Referred by/sample sent by (full name and address of Genetic Clinic (Referral note to be preserved carefully with case paper). Type of sample : Maternal blood/Chorionic villus sample/amniotic fluid/Foetal blood or other foetal tissue (Specify) 11—[3(i)] 7. Specify indication for prenatal 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 prenatal diagnosis : if abnormal, give details 10. Date(s) on which tests carried out The results of the prenatal (diagnostic tests were conveyed to. 11. Normal/Abnormal on.... Date Name, signature and Registration number of the Medical Geneticist Form F [See rule 9 NAME, ADDRESS AND REGISTRATION NO. OF GENETIC CLINIC RECORD TO BE MAINTAINED BY THE GENETIC CLINIC 1. Patient's name 3. Husband's /Father's name 4. Full Address with Tel. No., if any 5. Referred by (full name and address of Counselling Centre (Referral note to be preserved carefully with case papers)

6. Last menstrual period/,, 14 weeks of pregnancy

7. History of genetic/medical disease in the family (specify), Basis of diagnosis : (c) (d) Clinical Bio-Chemical Cyto-genetic (e.g. radiologist (specify) 30 THE GAZETTE OF INDIA : EXTRAORDINARY [PART II —SEC

8. Indication for prenatal 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) (vi) Any other (specify) 10. 11. 12. 13. 14. 15. 16

17. Any complication of procedure—please specify Laboratory tests recommended * (i) Chromosomal studies (i) Biochemical studies (ii) Molecular studies Result of pre-natal diagnostic procedure and specify abnormality detected, if any. Was MTP advised/conducted Date(s) on which procedures carried out. Date on which MTP carried out. Date on which consent obtained. The result of pre-natal diagnostic procedure were conveyed to Date Place * Strike out whichever is not applicable or not necessary. Normal/ Abnormal I Name, signature and Registration number of the Gynaecologist/Radiologist/Registered Medical Practitioner. age. FORM G [See rule 10(5)] FORM OF CONSENT .wife/daughter of years residing at.... hereby state that I have been explained fully the probable side effects and after effects of the pre-natal diagnostic 31 procedures. I wish to undergo the pre-natal diagnostic procedures in my interest to find out the possibility Of any abnormality (i.e. deformity or disorder) in the child I am carrying. I undertake not to terminate the pregnancy if the pre-natal procedure and any pre-natal tests conducted show the absence of deformity or disorders. I understand that the sex of the foetus will not be disclosed to me. I understand that breach of this undertaking will make me liable to penalty as prescribed in the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994). Date Place Signature I have explained the contents of the above consent to the patient and her companion (Name... .., relationship.... Date Address..... in a language she/they understand. Name, signature and Registration number of Gynaecologist Name, address and Registration number of Genetic Clinic FORM H [See rule 9(5)] PERMANENT RECORD OF APPLICATION FOR REGISTRATION, GRANT OF REGISTRATION, REJECTION OF APPLICATION FOR REGISTRATION AND RENEWALS OF REGISTRATION 2. 3. 4. 5. 6. 7, 9, File number of Appropriate Authority. Date of receipt of application for grant of registration. Name, Address, Phone/Fax etc, of Applicant. Name and address (es) of Genetic Counselling Centre* / Genetic Laboratory* / Genetic Clinic. * Date on which case considered by Advisory Committee and recommendation of Advisory Committee, in summary. Outcome of application (state granted/rejected/and date of issue of orders). Registration number allotted and date of expiry of registration. Renewals (date of renewal and renewed upto) 10. File number in which renewals dealt. 11. Additional information, if any. SQ Name, designation and signature of appropriate Authority 32 THE OAZWITE OF INDIA : EX'-ORDINARY 11 30] 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 "elsewhere-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 Counseling 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 Counseling 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 ditto, and every subsequent entry shall also be similarly authenticated. Printed by the Manager, Govt. of India Press, Ring Road, Mayapuri New Delhi-110064 and Published by the Controller of Publication', Delhi-110054, 1996

