PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION) RULES, 1996

THE PRE-CONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION) RULES, 1996 [GSR I(E), dt. 1-1-1996, w.e.f. 1-1-19961 [As amended vide GSR 492(E), dt. 22-5-2017, w.e.f. 23-5-20171 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[(1) These Rules may be called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996.1 2. I 2 3 4 5 (2) They shall come into force on the date of their publication in the Official Gazette. Definitions In these rules, unless the context otherwise requires,— (a) (b) (c) (e) (f) "Act" means the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994)2; "employee" means a person working in or employed by a 3 [Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre], and includes those working on part-time, contractual, consultancy, honorary or on any other basis; "Form" means a Form appended to these rules; xx x] "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 assigned to them in the Act; "Mobile Medical Unit" means a mobile vehicle which provides specialized facilities for the pa tients, requiring basic specialist services and Substituted Vide GSR 109(E), dt. 14-2-2003, w .e.f. 14-2-2003. prior to substitution sub-rule (1) stood as under: "(l) These rules may be called the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996." Now "The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994)." Substituted for "Genetic Counselling Centre, Genetic Labortory and Genetic Clinic" vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. Omitted, ibid. Prior to omission clause (d) stood as under. "(d) "Schedule" means a Schedule appended to these rules. Inserted vide GSR 80(E), dt. 7-2-2012. w.e.f. 9-2-2012. RULE 3 THE PRE-CONCEPTION AND PRE-NATAL.....RULES 1996 23 provides improved access to healthcare facilities and equitable distribution of health services at the doorsteps, across the country, especially in the underserved areas. (h) "Mobile Genetic Clinic" means a mobile medical unit where ultrasound machine or imaging machine or scanner or other equipment capable of determining sex of the foetus or a portable equipment which has the potential for detection Of sex during pregnancy or selection of sex before conception is used.] 1[3. Minimum requirements The qualifications of the employees, the requirement of equipment etc. for a Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall be as under: (l) Any person being or employing— (i) a gynaecologist or a paediatrician having six months' experience or four weeks' training in genetic counselling; or (ii) a medical geneticists, having adequate space and educational charts/models/equipments for carrying out genetic counselling may set up a genetic counselling center and get it registered as a genetic counselling center. (2)(a) Any person having adequate space and being or employing,— (i) a Medical Geneticist; and (ii) a laboratory technician, having a B.Sc. degree in Biological Sciences or a degree or diploma in medical laboratory course with at least one year experience in conducting appropriate pre-natal diagnostic techniques, tests or procedures, may set up a genetic laboratory. (b) Such laboratory should have or acquire such of the following equipments as may be necessary for carrying out chromosomal studies, bio-chemical studies and molecular studies:— (i) Chromosomal studies: (1) Laminar flow hood with ultraviolet and fluorescent light or Other suitable culture hood. (2) Photo-microscope with fluorescent source of light. (3) Inverted microscope. Incubator and oven. (5) Carbon dioxide incubator or closed system with 5% C02 atmosphere. (6) Autoclave. (7) Refrigerator. (8) Water bath. (9) Centrifuge (10) Vortex mixer. (11) Magnetic strirrer. (12) pH meter. Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. 24 THE PRE-CONCEPTION AND PRE-NATAL.....RULES 1996 RULE 3 (13) A sensitive balance (preferably electronic) with sensitivity milligram. (14) Double distillation apparatus (glass). (15) Such other equipments as may be necessary. (ii) Biochemical studies : (requirements according to tests to be carried out) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (13) (14) (15) (16) (17) (18) Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood. Inverted microscope. Incubator and oven. Carbon dioxide incubator or closed system with 5% C02 atmosphere. Autoclave. Refrigerator. Water bath. Centrifuge. Electrophoresis apparatus and power supply. Chromatography chamber. Spectro-photometer and Elisa reader or Radio-immunoassay system (with gamma beta-counter) or fluorometer for various biochemical tests. Vortex mixer. Magnetic stirrer. pH meter. A sensitive balance (preferably electronic) with sensitivity of O. 1 milligram. Double distillation apparatus (glass). Liquid nitrogen tank. Such other

equipments as may be necessary. (iii) Molecular studies: Inverted microscope. (1) (2) Incubator. (3) Oven. Autoclave. (4) Refrigerators (4 degree and minus 20 degree Centigrade). (5) W ater bath. (6) Microcentrifuge. (7) Electrophoresis apparatus and power supply. (8) (9) Vertex mixer. (10) Magnetic stirrer. (11) pH meter. A sensitive balance (preferably electronic) with sensitivity of O. 1 (12) milligram. Double distillation apparatus (glass). (13) P.C.R. machine. (14) Refrigerated centrifuge. (15) RULE 3A THE PRE-CONCEPTION AND PRE-NATAL.....„WLES 1996 25 (16) U.V. Illuminator With photographic attachment or other documentation system, (17) Precision micropipettes. (18) Such other equipments as may be necessary. (3)(1) Any person having adequate space and being or employing,— (a) Gynaecologist having experience of performing at least 20 procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis foetoscopy, foetal skin or organ biopsy or foetal blood sampling etc. under supervision of an experienced gynaecologist in these fields; or a sonologistor imaging specialist or registered medical practitioner having Post Graduate degree or diploma or six months' training duly imparted in the manner prescribed in the "the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (Six Months Training) Rules, 2014; orl (c) a medical geneticist, may set up a genetic clinic/ultrasound clinic /imaging centre. (2) The Genetic Clinic/ultrasound clinic/imaging centre should have or acquire such of the following equipments, as may be necessary for carrying out the tests or procedures— (a) (b) (c) (d) (e) (f) (g) (h) Equipment and accessories necessary for carrying out clinical examination by an obstetrician or gynaecologist. An ultra-sonography machine including mobile ultrasound machine, imaging machine or any other equipment capable of conducting foetal ultrasonography. Appropriate catheters and equipmen t for carrying out chorinoic villi aspirations per vagina or per abdomen. Appropriate sterile needles for amniocentesis or cordocentesis. A suitable foetoscope with appropriate accessories for foetoscopy, foetal skin or organ biopsy or foetal blood sampling shall be optional. Equipment for dry and wet sterilization. Equipment for carrying out emergency procedures such as evacuation of uterus or resuscitation in case of need. Genetic Works Station.] 21(3) Each medical practitioner qualified under the Act to conduct ultrasonography in a genetic clinic/ultrasound clinic/imaging centre shall be permitted to be registered with a maximum of two such clinics/centres within a district. The consulting hours for such medical practitioner, shall be clearly specified by each clinic/ centre.] 3[3A. Sale of ultrasound machines/imaging machines (1) No organization including a commercial organization or a person, including manufacturer, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment, capable of detecting sex of foetus, shall sell, distribute, supply, rent, allow or authorize the use Of any such machine or equipment in any manner, 1 Substituted videGSR 9-1-2014, w.e.f. 10-1-2014. 2 InsertedvideGSR 4-6-2012, w.ef. 5-6-2012. 3 Inserted vide GSR109(E), dt. 14-2-2003, wæ.f. 14-2-2003. 26 THE PRE-CONCEPTION AND PRE-NATAL.....RULES 1996 RULE 3B whether on payment or otherwise, to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person unless such Centre, Laboratory, Clinic, body or person is registered under the (2) The provider of such machine/ equipment to any person [body registered under the Act shall send to the concerned State / UT Appropriate Authority and to the Central Government, once in three months a list of those to whom the machine/ equipment has been provided. (3) Any organization or person, including manufacturer, importer, dealer or supplier of ultrasound machines / imaging machines or any other equipment capable of detecting sex of foetus selling, distributing, supplying or authorising, in any manner, the use of any such machine or equipment to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person registered under the Act shall take an affidavit from the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person purchasing or getting authorisation for using such machine/ equipment that the machine / equipment shall not be used for detection of sex of foetus or selection of sex before or after conception.] 1 [3B. Regulation of portable machines (1) The use of portable ultrasound machine or any other portable machine or device which has the potential for selection of sex before conception or detection of sex during pregnancy shall be permitted only in the following conditions, namely:— (a) the portable machine being used, within the premises it is registered, for providing services to the indoor patients; (b) as part of a mobile medical unit, offering a bouquet of other health and medical services. Explanation : For the purpose of this sub-rule, the expression "other health and medical services" means the host of services provided by the mobile medical unit which may include the following, namely:— (i)

Curative (a) Referral of complicated cases; (b) Early detection of TB, Malaria, Leprosy, Kala-Azar and other locally endemic communicable diseases and non-communicable diseases such as hypertension diabetes, cataract cases etc.; (c) Minor surgical procedures and suturing; (d) Specialist services such as O and G Specialist, Paediatrician and Physician; (ii) Reproductive and Child Health Services (a) (b) (c) (d) (e) (f) Ante natal check up and related services; Referral for complicated pregnancies; Promotion of institutional deliveries; Post-natal check up; Immunization clinics; Treatment of common childhood illness; 1 Inserted vide GSR 80(E), dt. 7-2-2012, w.e.f. 9-2-2012. RULE 4 THE PRE-CONCEPTION AND PRE-NATAL.....RULES 1996 27 (g) Treatment of Reproductive Tract Infection or Sexually Transmitted Infections; (h) Adolescents care such as lifestyle education, counselling, treatment of minor ailments. (iii) Family Planning Services (a) Counselling for spacing and permanent method; (b) Distribution of contraceptives. (iv) Diagnostic (a) Investigation facilities like haemoglobin, urine examination; (b) Clinical detection of leprosy tuberculosis or endemic diseases; (c) Screening of cancer etc. (v) Specialised facilities and services (a) X-ray; (b) ECG; (c) Ultrasound test. (vi) Emergency services and care in items Of disaster or epidemic or public health emergency or accidents etc. (2) Regulation of services to be offered by Mobile Genetic Clinic (a) A Mobile Genetic Clinic shall operate and offer pre-natal diagnostic techniques, only as part of a Mobile Medical Unit offering a bouquet of other health and medical services, in urban slums or rural or remote or hilly or hard to reach areas for improved access to health care services by underserved populations. (b) The machine under no circumstances shall be used for sex determination of the foetus. (c) The stand alone mobile ultrasound clinic offering only pre-natal diagnostic facilities are prohibited. (d) The mobile medical unit offering diagnostic services shall have adequate space for providing the facilities to patients. I 4. Registration of 1 [Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centrel An application for registration shall be made to the Appropriate Authority, in duplicate, in Form A, duly accompanied by an Affidavit containing— (i) an undertaking to the effect that the Genetic Centre/ Laboratory (Clinic/ Ultrasound Clinic / Imaging Centre / Combination thereof, as the case may be, shall not conduct any test or procedure, by whatever name called, for selection Of sex before or after conception or for detection of sex of foetus except for diseases specified in section 4(2) nor shall the sex of foetus be disclosed to any body; (ii) an undertaking to the effect that the Genetic Centre/ Laboratory/CliniC/ Combination thereof, as the case may be, shall display prominently a notice that they do not conduct any technique, test or procedure etc., by I Substituted for Genetic Counselling, Genetic Laboratory and Genetic Clinic" Vide GSR dt. 14-2-2003, w.e.f. 14-2-2003. 2 Substituted, ibid. Prior to Substitution sub-rule (l) stood as under: "(1) An application or registration shall be made to the Appropriate Authority, in duplicate, in Form A". 28 THE PRE-CONCEPTION AND PRE-NATAL.....RULES 1996 RULE 6 whatever name called, for detection of sex of foetus or for selection of sex before or after conception; and] The registration of a genetic clinic shall also include the registration of each and every mobile genetic clinic offering pre-natal diagnostic facilities as part of a medical mobile unit and such a vehicle has to be registered as a mobile genetic unit.] (2) The Appropriate Authority, or any person in his office authorized in this behalf, shall acknowledge receipt Of the application for registration, in the acknowledgement slip provided at the bottom of Form A, immediately if delivered at the office of the Appropriate Authority, or not later than the next working day if received by post. 2[5. Application Fee (1) Every application for registration under rule 4 shall be accompanied by an application fee of:— (a) 3 [Rupees twenty-five thousand] for Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre. (b) 4[Rupees thirty-five thousand] for an institute, hospital, nursing home, or any place providing jointly the service Of a Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic, Ultrasound Clinic or Imaging Centre or any combination thereof: PROVIDED that if an application for registration Of any Genetic Clinic/ Laboratory (Centre etc., has been rejected by the Appropriate Authority, no fee shall be required to be paid on re-submission Of the application by the applicant for the same body within 90 days of rejection: PROVIDED FURTHER tha t any subsequent applica tion shall be accompanied with the prescribed fee. Application fee once paid will not be refunded. (2) The application fee shall be paid by a demand draft drawn in favour of the Appropriate Authority, on any scheduled bank payable at the headquarters of the Appropriate Authority concerned. The fees collected by the Appropriate Authorities for registration Of Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre or any other body or person under sub-rule (1), shall be deposited by the Appropriate Authority concerned in a

bank account opened in the name of the official designation of the Appropriate Authority concerned and shall be utilized by the Appropriate Authority in connection with the activities connected with implementation of the provisions of the Act and these rules.] 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 tothe a licant. One copy Of the certificate Of registration shall be displayed by the registered [Genetic 1 2 3 4 5 Inserted vide GSR 80(E), dt. 7-2-2012, w.e.f. 9-2-2012. Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. Substituted for "Rs. 3,000.00" vide GSR 418(E), dt. 4-6-2012, w.ef 5-6-2012. Substituted for "Rs. 4,000.00", ibid. Substituted for 'Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic" vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. RULE 6 THE PRE-CONCEPTION AND PRE-NATAL..,,,...RULES 1996 29 Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre] at a conspicuous place at its place of business: PROVIDED that the Appropriate Authority may grant a certificate of registration to a Genetic Laboratory or a Genetic Clinic to conduct one or more specified pre-natal diagnostic tests or procedures, depending on the availability of place, equipment and qualified employees, and standards maintained by such laboratory or clinic. 11(2A) (a) One copy of the certificate of registration shall be displayed by the registered mobile medical unit inside the vehicle at a conspicuous place. (b) The certificate of registration for such unit, shall clearly specify the following:— (I) the area of its operation, which shall not exceed the district wherein it is registered; (11) the number of portable machines installed and being used in the vehicle; (Ill) the make and model number of the portable machine; (IV) the registration number Of the vehicle; (V) full address of the service provider for the mobile medical unit. (2B) The portable equipment used for conducting pre-natal diagnostic test shall be an integral part of the mobile medical unit and such equipment shall not be used outside such unit under any circumstances. (2C) In case of a breakdown of the vehicle of for any Other reason due to which the registered unit cannot be used as a Genetic Clinic, the Appropriate Authority has to be informed within a period of seven days.] (3) If, after enquiry and after giving an opportunity Of being heard to the applicant and having regard to the advice of the Advisory Committee, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of the Act and these rules, it shall, for the reasons to be recorded in writing, reject the application for registration and communicate such rejection to the applicant as specified in

Form C. (4) An enquiry under sub-rule (1), including inspection at the premises of the 2[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre], shall be carried out only after due notice is given to the applicant by the Appropriate Authority. (5) Grant of certificate of registration or rejection of application for registration shall be communicated to the applicant as specified in Form B or Form C, as the case may be, within a period or ninety days from the date of receipt of application for registration. (6) The certificate of registration shall be non-transferable. In the event Of change of ownership or change of management or on ceasing to function as a 2[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre], both copies of the certificate of registration shall be surrendered to the Appropriate Authority. (7) In the event of change of ownership or change of management of the 2[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging 1 2 Inserted vide GSR 80(E), dt. 7-2-2012, w.e.f. 9-2-2012. Substituted for "Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic" Vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. 30 THE PRE-CONCEFTION AND PRE-NATAL.....RULES, 1996 RULE 9 Centre], the new owner or manager of such Centre, Laboratory or Clinic shall apply afresh for grant of certificate of registration

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

8. Renewal of registration (1) An application for renewal of certificate of registration shall be made in duplicate in Form A, to the Appropriate Authority thirty days before the date Of expiry of the certificate of registration. Acknowledgement of receipt of such application shall be issued by the Appropriate Authority in the manner specified in sub-rule (2) of rule 4. (2) The Appropriate Authority shall, after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements Of the Act and these rules and having regard to the advice of the Advisory Committee in this behalf, renew the certificate of registration, as specified in Form B, for a further period of five years from the date of expiry of the certificate of registration earlier granted. (3) If, after enquiry and after giving an opportunity of being heard to the applicant and having regard to the advice of the Advisory Committee, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of the Act and these rules, it shall, for reasons to be recorded in writing, reject the application for renewal of certificate of registration and communicate such rejection to the applicant as specified in

Form C. (4) The fees payable for renewal of certificate of registration shall be one-half of the fees provided in sub-rule (1) of rule 5. (5) On receipt of the renewed certificate of registration in duplicate or on receipt of communication of rejection of application for renewal, both copies of the earlier certifica te of registration shall be surrendered immediately to the Appropriate Authority by the 1 [Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre]. (6) In the event of failure of the Appropriate Authority to renew the certificate of registration or to communicate rejection of application for renewal of registration within a period of ninety days from the date of receipt of application for renewal of registration, the certificate of registration shall be deemed to have been renewed

9. Maintenance and preservation of records Every Genetic Counselling Centre, Genetic Laboratory, 31Genetic Clinic including a Mobile Genetic Clinic], Ultrasound Clinic and Imaging Centre shall maintain a register showing, in serial order, the names and addresses of the men or women given genetic counselling, subjected to pre-natal diagnostic procedures or pre-natal diagnostic tests, the names of their spouse or father and the date on which they first reported for such counselling, procedure or test.] (2) The record to be maintained by every Genetic Counselling Centre, in respect of each woman counselled shall be as specified in

Form D. 1 2 3 Substituted for "Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic" vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. Substituted, ibid. Substituted for "Genetic Clinic" vide GSR 80(E), dt. 7-2-2012, w.e.f. 9-2-2012. RULE 10 THE PRE-CONCEPTION AND PRE-NATAL.....RULES 1996 31 record to be maintained by every Genetic Laboratory, in respect of each man or woman subjected to any pre-natal diagnostic procedure/ technique/test, shall be as specified in Form E. (4) The record to be maintained by every 21Genetic Clinic including a Mobile Genetic Clinic], in respect of each man or woman subjected to any pre-natal diagnostic procedure/ technique/test, shall be as specified in Form F.] (5) The Appropriate Authority shall maintain a permanent record of applications for grant or renewal of certificate of registration as specified in Form H. Letters of intimation of every change of employee, place, address and equipment installed shall also be preserved 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 3 [Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre] for a period of two years from the date of completion of counselling, pre-natal diagnostic procedure or pre-natal diagnostic test, as the case may be. In the event of any legal proceedings, the records shall 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 3 [Genetic Counselling Centres or Genetic Laboratory or Genetic Clinic or Ultrasound Clinic or Imaging Centre] maintains records on computer or other electronic equipment, a printed copy Of the record shall be taken and preserved after authentication by a person responsible for such record. 4[(8) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall send a complete report in respect of all pre-conception or pregnancy related procedures [techniques /tests conducted by them in respect of each month by 5th day of the following month to the concerned Appropriate Authority IO. Conditions for conducting pre-natal diagnostic procedures Before conducting preimplantation genetic diagnosis, or any pre-natal diagnostic technique/ test/ procedure such as amniocentesis, chorionic villi biopsy, foetoscopy, foetal skin or organ biopsy or cordocentesis, a written consent, as specified in Form G, in a language the person undergoing such procedure understands, shall be obtained from her / him:] PROVIDED that where a Genetic Clinic has taken a sample of any body tissue or body fluid and sent it to a Genetic Laboratory for analysis or test, it shall not be necessary for the Genetic Laboratory to obtain a fresh consent in Form G. 4[(1A) Any person conducting ultrasonography/ image scanning on a pregnant woman shall give a declaration on each report on ultrasonography / image scanning that he/she has neither detected nor disclosed the sex of foetus of the pregnant woman to any body. The pregnant woman shall before undergoing ultrasonography/image scanning declare that she does not want to know the sex of her foetus.] (2) All the State Governments and Union territories may issue translation Of Form G in languages used in the State or Union Territory and where no official translation in 1 2 3 4 5 Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. Substituted for "Genetic Clinic" vide GSR 80(E), dt. 7-2-2012, w.e.f. 9-2-2012. Substituted for 'Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic" vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. Inserted, ibid. Substituted , ibid. 32 THE PRE-CONCEPTION AND PRE-NATAL.....,,RULES 1996 RULE 12 a language understood by the pregnant woman is available, the Genetic Clinic may translate Form G into a language she understands. I Ill. Facilities for inspection (1) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre, nursing home, hospital, institute or any other place where any of the machines or equipments capable of performing any procedure, technique or test capable of pre-natal determination of sex or selection of sex before or after conception is used, shall afford all reasonable facilities for inspection of the place, equipment and records to the Appropriate Authority or to any other person authorised by the Appropriate Authority in this behalf for registration of such institutions, by whatever name called, under the Act, or for detection of misuse of such facilities or advertisement therefor or for selection of sex before or after conception or for detection/disclosure of sex of foetus or for detection of cases Of violation of the provisions of the Act in any other manner. The Appropriate Authority or the officer authorised by it may seal and seize any ultrasound machine, scanner or any other equipment, capable of detecting sex of foetus, used by any organisation if the organisation has not got itself registered under the Act. These machines of such organisations shall be confiscated and further action shall be taken as per the provisions of section 23 of the Act.] 12. Procedure for search and seizure The Appropriate Authority or any officer authorized in this behalf may enter and search at all reasonable times any Genetic Counselling Centre, Genetic

Laboratory, Genetic Clinic, Imaging Centre or Ultrasound Clinic in the presence of two or more independent witnesses for the purposes of search and examination of any record, register, document, book, pamphlet, advertisement, or any other material object found therein and seal and seize the same if there is reason to believe that it may furnish evidence of commission of an offence punishable under the Act. Explanation : In these rules— (I) 'Genetic Laboratory/Genetic Clinic/Genetic Counselling Centre' would include an ultrasound centre/ imaging centre/nursing home/ hospital/ institute or any other place, by whatever name called, where any of the machines or equipments capable of selection of Sex before or after conception or performing any procedure technique or test for prenatal detection of sex of foetus, is used; (2) 'material object' would include records, machines and equipments; and (3) 'seize' and 'seizure' would include 'seal' and 'sealing' respectively.] (2) A list of any document, record, register, book, pamphlet, advertisement or any other material object found in the 31Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre] and seized shall be prepared duplicate at the place of effecting the seizure. Both copies of such list shall be signed on 1 2 3 Substituted vide GSR 14-2-2003, w.e.f. 14-2-2003. Substituted vide GSR 426(E), dt. 31-5-2011 , w.e.f. 2-6-2011. Prior to substitution, sub-rule (2) read as under. "(2) The Appropriate Authority or the officer authorised by it may seal and seize any ultrasound machine, scanner or any other equipment, capable of detecting sex of foetus, used by any organisation if the organisation has not got itself registered under the Act. These machines of the organisations may be released if such orgaisation pays penalty equal to five times of the registration fee to the Appropriate Authority concerned and gives an undertaking that it shall not undertake detection of sex of foetus or selection of sex before or after conception. " Substituted for "Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic" vide GSR dt. 14-2-2003, w.e.f. 14-2-2003. RULE 14 THE PRE-CONCEPTION AND PRE-NATAL.....RULES 1996 33 every page by the Appropriate Authority or the officer authorized in this behalf and by the witnesses to the seizure: PROVIDED that the list may be prepared, in the presence of the witnesses, at a place other than the place of seizure if, for reasons to be recorded in writing, it is not practicable to make the list at the place of effecting the seizure. (3) One copy Of the list referred to in sub-rule (2) shall be handed over, under acknowledgement, to the person from whose custody the document, record, register, book, pamphlet, advertisement or any other material object have been seized: PROVIDED that a copy of the list of such document, record, register, book, pamphlet, advertisement or other material object seized may be delivered under acknowledgement, or sent by registered post to the owner or manager of the 1[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre], if no person acknowledging custody of the document, record, register, book, pamphlet, advertisement or other material object seized is available at the place of effecting the seizure. (4) If any material Object seized is perishable in nature, the Appropriate Authority, or the officer authorized in this behalf shall make arrangements promptly for sealing, identification and preservation of the material object and also convey it to a facility for analysis or test, if analysis or test be required: PROVIDED that the refrigerator or Other equipment used by the 1[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre] for preserving such perishable material object may be sealed until such time as arrangements can be made for safe removal of such perishable material object and in such eventuality, mention of keeping the material object seized, on the premises of the 1 [Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre] shall be made in the list of seizure. (5) In the case of non-completion of search and seizure operation, the Appropriate Authority or the officer authorized in this behalf may make arrangements, by way of mounting a guard or sealing of the premises of the I [Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre], for safe keeping, listing and removal of documents, records, book or any Other material object to be seized, and to prevent any tampering with such documents, records, books or any other material object

13. Intimation of changes in employees, place or equipment Every 1[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre] shall intimate every chan of employee, place, address and equipment installed, to the Appropriate Authority atleast thirty days in advance of the expected date of such change, and seek re-issuance of certificate of registration from the Appropriate Authority, with the changes duly incorporated]

14. Conditions for analysis or test and pre-natal diagnostic procedures (1) No Genetic Laboratory shall accept for analysis or test any sample, unless referred to it by a Genetic Clinic.1 2 Substituted

for 'Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic" vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. Substituted for "within a period of thirty days of such change" vide GSR418(E), dt. 4-6-2012, w.e.f. 5-6-2012. 34 THE PRE-CONCEPTION AND PRE-NATAL.....RULES 1996 RULE 18 (2) Every pre-natal diagnostic procedure shall invariably be immediately preceded by locating the foetus and placenta through ultrasonography, and the pre-natal diagnostic procedure shall be done under direct ultrasonographic monitoring so as to prevent any damage to the foetus and placenta

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

16. Allowances to members of the Central Supervisory Board (1) The ex-oficio members, and other Central and State Government officers appointed to the Board will be entitled to Travelling Allowance and Daily Allowance for attending the meetings of the Board as per the Travelling Allowances Rules applicable to them.(2) The non-official members appointed to, and Members of Parliament elected to, the Board will be entitled to Travelling Allowance and Daily Allowance or attending the meetings of the Board as admissible to non-official and Members of Parliament as the case may be, under the Travelling Allowances rules of the Central Government

17. Public Information (1) Every 1[Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre] shall prominently display on its premises a notice in English and in the local language or languages for the information of the public, to the effect that disclosure of the sex of the foetus is prohibited under law.(2) At least one copy each of the Act and these rules shall be available on the premises Of every 1 [Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre] and shall be made available to the clientele on demand for perusal. (3) The Appropriate Authority, the Central Government, the State Government, and the Government/ Administration of the Union Territory may publish periodically lists of registered 1[Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinic and Imaging Centre] and findings from the reports and other information in their possession, for the information of the public and for use by the experts in the field. 2[18. Code of Conduct to be Observed by persons working at Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics, Imaging Centres etc. All persons including the owners, employee or any other persons associated with Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics, Imaging Centres registered under the Act / these Rules shall— 1 2 (i)not conduct or associate with, or help in carrying out detection or disclosure Of sex of foetus in any manner; (ii)not employ or cause to be employed any person not possessing qualifications necessary for carrying out pre-natal diagnostic techniques/ procedures, techniques and tests including ultrasonography; (iii)not conduct or cause to be conducted or aid in conducting by himself or through any other person any techniques or procedure for selection of sex Substituted for "Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic" vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. Inserted, ibid. RULE 18A THE PRECONCEPTION AND PRE-NATAL..,,,...RULES 1996 35 before or after conception or for detection of sex of foetus except for the purposes specified in sub-section (2) of section 4 of the Act; (iv)not conduct or cause to be conducted or aid in conducting by himself or through any other person any techniques or test or procedure under the Act at a place other than a place registered under the Act/ these Rules; (v)ensure that no provision of the Act and these Rules are violated in any manner; (vi)ensure that the person, conducting any techniques, test or procedure leading to detection of sex of foetus for purposes not covered under section 4(2) of the Act or selection of sex before or after conception, is informed that such procedures lead to violation of the Act and these Rules which are punishable offences; (vii)help the law enforcing agencies in bringing to book the violators of the provisions of the Act and these Rules; (viii)display his/her name and designation prominently on the dress worn by him /her; (ix)write his/her name and designation in full under his / her signature; (x)on no account conduct or allow/cause to be conducted female foeticide; (xi)not commit any other act of professional misconduct.] 1 [18A. Code of Conduct to be observed by Appropriate Authorities (I) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following general code of conduct, namely.— (i) maintain dignity, and integrity at all times; (ii) observe and implement the provisions of the Act and Rules in a balanced and standardised manner in the course of their work; (iii) conduct their work in a just manner without any bias or a perceived presumption of guilt; (iv) refrain from making any comments which demean individuals on the basis of gender, race, religion; (v) delegate his or her powers by administrative order to any authorised officer in his or her absence and preserve the order of authorisation as documentary proof for further action. (2) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following Conduct for Advisory Committees, namely:— (i) ensure that the re-constitution, functions and other relevant matters related to advisory committee shall be in accordance with the provisions Of the Advisory Committee Rules, 1996; (ii) ensure that a person Who is the part Of investigating machinery in cases under the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994), shall not be nominated or appointed as a member of the Advisory Committee; (iii) ensure that the process of filling up of vacancies in Advisory Committee shall start at least ninety days before the probable date of the occurrence of vacancy; 1 Inserted vide GSR 119(E), dt.24-2-2014, w.e.f. 26-2-2014. 36 THE PRE-CONCEPTION AND PRE-NATAL....,,.WLES 1996 RULE (iv) ensure that no person shall participate as a member or a legal expert Of the Advisory Committee if he or she has conflict of interest; (v) conduct frequent meetings of the Advisory Committee to expedite the decisions regarding renewal, cancellation and suspension of registration. (3) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for

processing of complaint and investigation, namely (i) maintain appropriate diaries in support Of registration of each of the complaint or case under the Act; (ii) attend to all complaints and maintain transparency in the follow-up action of the complaints; (iii) investigate all the complaints within twenty-four hours of receipt of the complaint and complete the investigation within forty-eight hours of receipt of such complaint; (iv) as far as possible, not involve police for investigating cases under the Act as the cases under the Act are tried as complaint cases under the Code of Criminal Procedure, 1973 (2 of 1974). (4) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for registration and renewal of applications under the Act, namely:— (i) dispose of the application for renewal and new registration within a period of seventy days from the date Of receipt of application; l[(ii) ensure that no application for fresh registration or renewal of registration IS accepted if any case is pending in any court against the applicant for violation of any provision of the Act and the rules made thereunder]. (5) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for Legal Action, namely:— (i) (ii) (iii) (iv) (v) (vi) ensure that protection and expensses of witness shall be met from the registration amount collected; ensure that all the notifications of the Government be produced in original in the court and a copy of the same be preserved; ensure that while filing the cases, all the papers, records, statements, evidene, panchnama and other material objects attached to the case file shall be in original; suspend the certificate of registration in the course of taking legal action Of seizure and sealing of the facility; ensure that there shall be no violation of the provisions Of the Medical Termination of Pregnancy Act, 1971 (34 of 1971) and the Rules made thereunder while implementing the provisions of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996; take immediate action for filing appeal, revision or other proceeding higher courts in case of order of acquittal within a period of thirty days but not later than fifteen days of receipt of the order of acquittal. (6) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall submitt quarterly progress report to the I Substituted vide GSR 60(E), dt. 28-1-2015, w.e.f. 28-1-2015. prior to substitution, clause (ii) read as under : "(ii) ensure that no application for fresh registration or renewal is accepted if any case is pending in any court against the applicant" RULE 18A THE PRE-CONCEPTION ANDPRE-NATAL..,,...RULES 1996 37 Government of India through State Government and maintain Form H for keeping the information of all the registrations made readily available. (7) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following regulation of ultrasound equipmets, namely:— (i) monitor the sales and import of ultrasound machines including portable or buyback, assembled, gift, scrap or demo; (ii) ensure regular quartely reports from ultrasound manufacturers, dealers, wholesalers and retailers and any person dealing with the sales of ultrasound machines at the State level; (iii) conduct periodical survey and audit of all the ultrasound machines sold and operating in the State or district to identify the unregistered machines; (iv) file complaint against any owner Of the unregistered ultrasound machine and against the seller of the unregistered ultrasound machine. (8) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for inspection and monitoring, namely:— (i) conduct regular inspection of all the registered facilities once in every ninety days and shall preserve the inspection report as documentary evidence and a copy of the same be handed over to the owner of facility inspected and obtain acknowledgement in respect of the inspection; (ii) place all the inspection reports once in three months before the Advisory Committee for follow up action; (iii) maintain bimonthly progress report containing number of cases filed and persons convicted, registration made, suspended or cancelled, medical licenses cancelled, suspended, inspections conducted, Advisory Committee meetings held at the district level and quarterly progress report at the State level; (iv) (a) procure the copy of the charges framed within seven days and in the case of doctors, the details of the charges framed shall be submitted within seven days of the receipt of copy of charges framed to the State Medical Council; (b) procure the certified copy of the order of conviction as soon as possible and in the case of conviction ofthe doctors, the certified copy of the order of conviction shall be submitted within seven days of the receipt of copy of the order Of conviction. (9) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall observe the following conduct for accountability, namely:— (i) obtain prior sanction or approval of the Government of India for any resolution concerning the implementation of the provisions of the Act; (ii) take action, if any, under the

Act and immediately on receipt of notice under clause (b of sub-section (1) of section 28 of the Act and if he or she fails to do so, shall not be entitled for the protection under section 31 of the said Act and defend the case in his or her own capacity and at his or her own cost. (IO) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall follow the following financial guidance, namely:— 38 THE PRE-CONCEPTION AND PRE-NATAL.....RULES 1996 RULE 19A (i) maintain a separate and independent bank account operated by officers, at all levels; (ii) ensure transparency and adherence to standard Government financial norms for disbursement of money.] 1[19. Appeals (I) Anybody aggrieved by the decision of the Appropriate Authority at sub-district level may appeal to the Appropriate Authority at district level within 30 days of the order of the sub-district level Appropriate Authority. (2) Anybody aggrieved by the decision of the Appropriate Authority at district level may appeal to the Appropriate Authority at State/ UT level within 30 days of the order of the District level Appropriate Authority. (3) Each appeal shall be disposed of by the District Appropriate Authority or by the State/ Union Territory Appropriate Authority, as the case may be, within 60 days of its receipt. (4) If an appeal is not made within the time as prescribed under sub-rule (1), (2) or (3), the Appropriate Authority under that sub-rule may condone the delay in case he/ she is satisfied that appellant was prevented for sufficient cause from making such appeal. I 2119A. The manner for filing and disposal of the appeal under clauses (i) and (ii) of 1 2 section 21 of the Act (1) (a) The Central Government may, by notification in the Official Gazette, appoint a Central Appellate Authority for each of the Union territories, for the purpose of hearing appeal against the order of the Central Appropriate Authority or the Union territory Appropriate Authority. (b) TheCentra1 Appellate Authority shall consist Of an officer not below the rank of the Union territory Appropriate Authority. (2) (a) TheStateGovernmentmay,bynotificationin theOfficialGazette,appoint a State Appellate Authority for the whole State, for the purpose of appeal against the order of State Appropriate Authority. (b) The State Appellate Authority shall consist of the Principal Secretary, Health and Family Welfare or an officer not below the rank of the State Appropriate Authority as notified by the State Government. (3) (a) An appeal against the order Of suspension or cancellation of registration passed by the Central Appropriate Authority or the Union territory Appropriate Authority shall lie with the Central Appellate Authority. (b) An appeal against the order of suspension or cancellation of registration passed by the State Appropriate Authority shall lie with the State Appellate Authority appointed by the State Government. (4) An appeal to the Central Appellate Authority or the State Appellate Authority (a) be made in the form of a memorandum of appeal specified in

Form-I; (b) be accompanied by an Affidavit explaining the facts of the case, specified in Form-J and Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. Inserted vide GSR 492(E), dt. 22-5-2017, w.e.f. 23-5-2017. RULE 19A THE PRE-CONCEPTION AND 1996 39 (c) contain an index, synopsis and list Of documents as specified in Appendix-A. (5) Every appeal before the Central Appellate Authority or the State Appellate Authority shall be supported by the following documents, namely:— (a) self-certified copies of orders or documents against which appeal is being preferred; (b) copies of documents relied upon by the appellant; (c) index to the appeal; and (d) synopsis containing particulars of events and list of documents. (6) Every appeal shall be filed within a period of thirty days of the date of receipt of the order against which the appeal is preferred: PROVIDED that the Central Appellate Authority or the State Appellate Authority may allow the appeal after the period of thirty days, if there is a sufficient cause for not filing the appeal within the said period. (7) 'Ihe Central Appellate Authority or the State Appellate Authority shall issue notice to the respondent, which shall be served in any of the following modes, namely:— (a) (b) (c) (d) (b) (c) (d) (e) service by the appellant; or by hand delivery (dasti); or by registered post with acknowledgement due; or by electronic mail of fax. The Central or the State Appellate Authority shall hear the parties on receipt Of the appeal and shall intimate the date of hearing which shall be seven days before the date of hearing, by e-mail or courier at the address mentioned in the appeal. The appellant may present in person or through his duly authorised legal representative, at the time of hearing of the appeal. If the appellant fails to appear before the Central Appellate Authority or the State Appellate Authority on the specific date, the appeal may be dismissed for default. The Central Appellate Authority or the State Appellate Authority may, if sufficient cause is shown, at any stage of appeal, grant time to the parties or to any of them and may from time to time adjourn the hearing of the appeal for reasons to be recorded in writing: PROVIDED that more than three adjournments shall not be given to the appellant. The Appeal shall be disposed of within a period of sixty days from the date of filing of the appeal. (9) The Central Appellate Authority or the State Appellate Authority shall dispose of the appeal by passing a speaking order in writing and issue under the seal of the Central Appellate Authority or the State Appellate Authority duly authenticated by the officer authorised by the Central Appellate Authority or the State Appellate Authority for this purpose within a period of sixty days from the date of receipt of the appeal.) 40 THE PRE-CONCEPTION ANDPRE-NATAL.....RULES, 1996 FORM-I [Refer rule 19A(4)(a)l BEFORE THE CENTRAL APPELLATE AUTHORITY OR THE STATE APPELLATE AUTHORITY APPEAL NO. (20 In the matter of: NAME AND ADDRESS OF APPELLANT NAME AND ADDRESS OF THE AUTHORITY WHOSE ORDER IS CHALLENGED Most respectfully showeth: FORM-I Appellant Respondent The above mentioned appellant appeals against the order passed by concerned Appropriate Authority at the..... (Name of place and address) against the appellant in (details of the case if any) and sets forth the following grounds of objection of the order dated.....,... appealed:— Particulars of the order including number of order, if any, against which 1. the appeal is preferred Brief facts of the case 2. Findings of the Appropriate Authority challenged 3. Grounds of appeal 4. Copy of the order enclosed along with all the documents relied upon by 5, the Appellant Any other information/ documents in support of appeal 6

7. Prayer That the appellant, therefore prays for the reasons stated above and as may be argued at the time of hearing, the records and proceedings be called for, this appeal be allowed, the order under the appeal be set aside and quashed, and order deemed just and proper may kindly be passed favour of the appellant. Signature of the Appellant Place Date Verification . do hereby verify that the contents Of para to are true and correct to the best of my knowledge and belief and no part is false and nothing material has been concealed therein. Signature of the Appellant AUTHORITY In the matter of: NAME OF THE APPELLANT VERSUS CONCERNED APPROPRIATE AUTHORITY AFFIDAVIT 1. APPENDIX-A THEPRE-CONCEPTION AND PRE-NATAL.....RULES 1996 41 FORM-J [Refer rule PROFORMA AFFIDAVIT BEFORE THE CENTRAL APPELLATE AUTHORITY OR THE STATE APPELLATE aged Appellant Respondent . .....doherebysolemnlydeclareasunder: 1. That Iam the Appellant in the captioned matter filed before the Appellate Authority and aware of all the facts and circumstances of the case, hence competent to swear this affidavit

2. That the accompanying Memo of Appeal has been drafted by my counsel under my instruction and the same has been understood by me, the same may be read as the part and parcel of this affidavit, and the same has not been repeated here for the sake of brevity. Deponent Verification

Verified on this day ....,, of (month and year) that the contents of the appeal are true and correct on the basis of my knowledge/ records/ documents/ legal advice received from the counsel and nothing material has been concealed therefrom. APPENDIX-A [Refer Rule BEFORE THE CENTRAL APPELLATE AUTHORITY OR THE STATE APPELLATE AUTHORITY In the matter of: NAME OF THE APPELLANT VERSUS CONCERNED APPROPRIATE AUTHORITY Appellant Respondent S.No. Index Particulars Signature of the Appellant 42 THE PRE-CONCEPTION AND PRE-NATAL.....RULES, 1996 SCHEDULE 1 Date S. No. Synopsis Particulars o events Signature Of the Appellant LIST OF DOCUMENTS Particulars Signature Of the Appellant [SCHEDULE 1 [Refer rule 3(1)J 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. Italicised Schedules I, 11 and Ill omitted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. SCHEDULE 11 THE PRE-CONCEPTION AND PRE-NATAL.....RULES 1996 43 SCHEDULE 11 [Refer rule 3(1)] REQUIREMENTS FOR REGISTRATION OF A GENETIC LABORATOR Y A. PLACE A room with adequate space for carrying out tests. B. EQUIPMENT These are categorised separatelyfor each of the under-mentioned studies. Chromosomal studies: (1) (2) (3) (5) (6) (7) (8) (9) (10) (11) (12) (13) (14) Laminar flow-hood with ultraviolet andfluorescent light or other suitable culture Photo-microscope with fluorescent source of light. Inverted microscope. Incubator and oven. Carbon-dioxide incubator or closed system with 5% C02 atmosphere. Autoclave. Refrigerator. Water bath. Centrifuge. Vortex mixer. Magnetic stirrer. pH meter. A sensitive balance (preferable electronic) with sensitivity of 0.1 miligram. Double distillation apparatus (glass). Biochemical studies: (requirements according to tests to be carried out) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (13) (14) (15) (16) (17) Laminar flow-hood with ultraviolet andfiuorescent light or other suitable culture Inverted microscope. Incubator and oven. Carbon-dioxide incubator or closed system with 5% C02 atmosphere. Autoclave. Refrigerator. Water bath. Centrifuge. Electrophoresis apparatus and power supply. Chromatography chamber. Spectro-photometer and Elisa reader or Radio-immunoassay system (with gamma beta-counter) or fluorometer for various biochemical tests. Vortex mixer. Magnetic stirrer. pH meter. A sensitive balance (preferable electronic) with sensitivity miligram. Double distillation apparatus (glass). Liquid nitrogen tank. Molecular studies: (1) Inverted microscope. (2) Incubator. 44 THE PRE-CONCEPTION AND PRE-NATAL.....RULES, 1996 SCHEDULE 111 (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (13) (15) (16) (17) Oven. Autoclave. Refrigerators (4 degree and minus 20 degree Centrigrade) Water bath. Microcentrtifuge. Electrophoresis apparatus and power supply. Vortex mixer. Magnetic stirrer. pH meter. A sensitive balance (preferable electronic) With sensitivity of 0.1 miligram. Double distillation apparatus (glass). P.C.R. machine. Refrigerated centrifuge. 11. V. Illuminator with photographic attachment or other documentation system. 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 111 [Refer rule REQUIREMENTS FOR REGISTRATION OF A GENETIC CLINIC A. PLACE A room with an area of twenty (20) square metres with appropriate aseptic arrangements. B. EQUIPMENT (1) Equipment and accessories necessary for carrying out clinical examination by obstetrician/gynaecologist. (2) Equipment, accessories, necessary for other facilities required for operations envisaged in the Act. An ultra-sonography machine. *(b) Appropriate cathethers and equipmentforcarryingout chorionicvilli aspirations per vagina or per abdomen. *(c) Appropriate sterile needles for amniocentesis or cordocentesis. (d) A with an appropriate accessoriesforfoetoscopy,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 Practitionerfor carrying out ultrasonography. The required experience shall be 100 cases under supervision of a similarly

qualified person experienced in these techniques. FORM A THE PRE-CONCEPTION AND PRE-NATAL..,,...RULES 1996 45 * These constitute the minimum requirement of equipment for conducting the relevant proce- dure.J I [FORM A [Refer rules 4(1) and (To be submitted in Duplicate with supporting documents as enclosures) APPLICATION FOR REGISTRATION OR RENEWAL OF REGISTRATION OF A GENETIC COUNSELLING CENTRE/ GENETIC LABORATORY /GENETIC CLINIC/ ULTRASOUND CLINIC /IMAGING CENTRE 1. Name of the applicant (Indicate name of the organisation sought to be registered) 2. Address of the applicant 3. Type of facilitiy to be registered (Please specify whether the application is for registration of a Genetic Counselling Centre/Genetic Laboratory/ Genetic Clinic/ Ultrasound Clinic [Imaging Centre or any combination of these.) 4. Full nameand address/addressesofGeneticCounsellingCentre/GenetiC Laboratory/Genetic Clinic/ Ultrasound Clinic/lmaging Centre with Telephone / Fax number(s) / Telegraphic/ Telex/ E-mail address(es)

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

6. Type of Institution (Govt. Hospital/Municipal Hospital [Public Hospital/ Private Hospital / Private Nursing Home/ Private Clinic/Private Laboratory /any other to be stated)

7. Specific pre-natal diagnostic procedures/ tests for which approval is sought.(a) Invasive (b) Non-lnvasive (i) amniocentesis/ chorionic villi aspiration/ chromosomal /biochemical /molecular studies Ul trasonography Leave blank if registration is sought for Genetic Counselling Centre only

8. Equipment available with the make and model of each equipment (List to be attached on a separate sheet).9. (a) Facilities available in the Counselling Centre. (b) Whether facilities are or would be available in the Laboratory/ Clinic for the following tests: (i) Ultrasound (ii) Amniocentesis (iii) Chorionic villi aspiration (iv) Foetoscopy (v) Foetal biopsy (vi) Cordocentesis 1 SubstitutedvideGSR wæ.f. 14-2-2003. 46 THEPRE-CONCEPTION ANDPRE-NATAL.....RULES 1996 FORM A (c) Whether facilities are available in the Laboratory/C1inic for the following: (i) Chromosomal studies (ii) Biochemical studies (iii) Molecular studies (iv) Preimplantation genetic diagnosis 10. Names, qualifications, experience and registration number of employees (may be furnished as an enclosure) 11. State whether the Genetic Counselling Centre / Genetic Laboratory / Genetic Clinic / Ultrasound Clinic / Imaging centrel qualifies for registration in terms of requirements laid down in rule 3. 12, For renewal applications only: (a) Registration No. (b) Date Of issue and date of expiry of existing certificate Of registration

13. List of Enclosures: (Please attach a list of enclosures/ supporting documents attached to this application.) Date : Place : l, Sh./Smt./Kum./Dr.. . years resident of . Name, designation and signature of the person authorised to sign on behalf of the organisation to be registered. DECLARATION son/daughter/wife of aged working as (indicate designation) . in (indicate name of the organisation to be registered) . hereby declare that I have read and understood the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994)2 and the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996.3 I also undertake to explain the said Act and Rules to all employees of the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/ Ultrasound clinic/ Imaging centre in respect of which registration is sought and to ensure that Act and Rules are fully complied with. Date : Place: Name, designation and signature of the person authorized to sign on behalf of the organisation to be registered 2 3 Strike out whichever is not applicable or not necessary. All enclosuresare to be by signature of the applicant. Read as "The Pre-conception and pre-natal Diagnostic Techniques (Prohibition Of Sex Selection) Act, 1994 (57 of 1994)" Read as "The Pre-conception and Pre-natal Diagnostic (Prohibition of Selection) Rules, 1996" FORM B THE PRE-CONCEPTION AND PRE-NATAL.....RULES 1996 47 [SEAL OF THE ORGANISATION SOUGHT TO BE REGISTERED] ACKNOWLEDGEMENT [Refer rules and 8(1)] The application in Form A in duplicate for grant* / renewal* of registration of Genetic Counselling Centre* / Genetic Laboratory* / Genetic Clinic* / Ultrasound Clinic* / Imaging Centre* by (Name and address of applicant) has been received by the Appropriate Authority .....,,..... On (date). *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 Authority, or authorised person in the Office of the Appropriate Authority Date: Place : *Strike out whichever is not applicable or not necessary. All enclosures are to be authenticated by signature of the applicant. SEAL] ORIGINAL/ DUPLICATE FOR DISPLAY I[FORM B [Refer rules 6(2), 6(5) and 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),2 the Appropriate Authority hereby grants registration to the Genetic Counselling Centre* / Genetic Laboratory* / Genetic Clinic* / Ultrasound Clinic* / Imaging Centre* named below for purposes of carrying out Genetic Counselling / Pre-natal Diagnostic Procedures* / Pre-natal Diagnostic Tests/ ultrasonography under the aforesaid Act for a period of five years ending on 2. This registration is granted subject to the aforesaid Act and Rules framed thereunder and any contravention thereof shall result in suspension or cancellation of this Certificate of Registration before the expiry Of the said period of five years apart from prosecution. A. Name and address of the Genetic Counselling Centre*/Genetic Laboratory* / Genetic Clinic* / Ultrasound Clinic* / Imaging Centre*. B. Pre-natal diagnostic procedures* approved for (Genetic Clinic). Non-lnvasive 1 Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. 2 Read as *'The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994)" 48 THE PRE-CONCEPTION AND PRE-NATAL.,,....RULES, 1996 (i) Ultrasound Invasive (ii) Amniocentesis (iii) Chorionic villi biopsy (vi) Foetoscopy. (v) Foetal skin or organ biopsy (vi) Cordocentesis (vii) Any other (specify) . To .....,,

FORM C C. Pre-natal diagnostic tests* approved (for Genetic Laboratory). (i) Chromosomal studies (ii) Biochemical studies (iii) Molecular studies D. Any other purpose (please specify) 3. Model and make of equipments being used (any change is to be intimated to the Appropriae Authority under rule 13)

4. Registration No.allotted

5. Period of validity of earlier Certificate Of Registration.(For renewed Certificate of Registration only) From 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 PLACES AT THE PLACE OF BUSINESS I [

FORM C [Refer rules 6(3), 6(5) and 8(3)] REJECTION OF APPLICATION FOR GRANT/RENEWAL OF REGISTRATION In exercise of the powers conferred under section 19(2) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994,2 the Appropriate . hereby rejects the application for grant* /renewal* of registration Authority. of the undermentioned Genetic Counselling Centre*/Genetic Laboratory* / Genetic Clinic* /Ultrasound Clinic* / Imaging Centre*. (1) Name and address Of the Genetic Counselling Centre* /Genetic Laboratory* /Genetic Clinic* / Ultrasound Clinic* / Imaging Centre*. (2) Reasons for rejection of application for grant/renewal of registration: Date: Place: Signature, name and designation of the Appropriate Authority with SEAL of Office * Strike out whichever is not applicable or necessary.] 1 Substituted vide GSR w.e.f. 14-2-2003. 2 Read as "The PR-conception and Pre-natal Diagnostic Techni ques (Prohibiti Of Sex Selection) Act, 1994 (57 of 1994)" FORM D 1. 2. 3. 4. 5. 6. 7. 8. 9. IO. 11

FORM D [Refer rule 9(2)] MAINTENANCE OF RECORDS BY THE GENETIC COUNSELLING CENTRE Name and address of Genetic Counselling Centre. Registration No. Patient's name Age 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) Cytogenetic (d) Other (e.g. radiological, ultrasonography) Indication for pre-natal diagnosis A. Previous child/children with: (i) Chromosomal disorders (ii) Metabolic disorders (iii) Congenital anomaly (iv) Mental retardation (v) Haemoglobinopathy (vi) Sex linked disorders (vii) Single gene disorder (viii) Any other (specify) B. Advanced maternal age (35 years or above) C. Mother / father / sibling having genetic disease (specify) D. Others (specify) Procedure advised2 (i) Ultrasound (ii) Amniocentesis (iii) Chorionic villi biopsy (iv) Foetoscopy (v) Foetal skin or organ biopsy (vi) Cordocentesis (vii) Any other (specify) Laboratory tests to be carried out 1 2 Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. Strike out whichever is not applicable or necessary 50 THE PRE-CONCEVI'ION AND PRE-NATAL.....RULES 1996 (i) Chromosomal studies (ii) Biochemical studies (iii) Molecular studies FORM E Normal / Abnormal 13. 14. 15

16. Place : Date:] (iv) Preimplantation genetic diagnosis Result of diagnosis If abnormal give details. Was MTP advised? Name and address of Genetic Clinic to which patient is referred. Dates of commencement and completion of genetic counseling. Name, Signature and Registration No. of the Medical Geneticist/Gynaecologist/Paediatrician administering Genetic Counselling. I [FORM E [Refer rule 9(3) MAINTENANCE OF RECORDS BY GENETIC LABORATORY I. 2. 3. 4. 5. 6. 7. 8. 9. IO. Name and address of Genetic Laboratory Registration No. Patient's name Age 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 papers) Type of sample : Maternal blood/Chorionic villus sample/amniotic fluid/ Foetal blood or other foetal tissue (specify) Specify indication for pre-natal diagnosis A. Previous child/ children with (i) Chromosomal disorders (ii) Metabolic disorders (iii) Malformation(s) (iv) Mental retardation (v) Hereditary haemolytic anaemia (vi) Sex linked disorder (vii) Single gene disorder (viii) Any other (specify) B. Advanced maternal age (35 years or above) C. Mother/ father / sibling having genetic disease (specify) D. Other (specify) Laboratory tests carried out (give details) 1 Substituted vide GSR 109(E), dt. 14-2-2003, we.f. 14-2-2003. FORM F on THE PRE-CONCEPTION AND PRE-NATAL.....RULES 1996 51 (i) Chromosomal studies (ii) Biochemical studies (iii) Molecular studies (iv) Preimplantation gentic diagnosis 11. Result of diagnosis If abnormal give details

12. Date(s) on which tests carried out. Normal/ Abnormal The results Of the Pre-natal diagnostic tests were conveyed to Place : Date:] Name, Signature and Registration No. Of the Medical Geneticist/ Director of the Institute *Strike not whichver is not applicable or necessary. I[FORM F [Refer proviso to section 4(3), rules 9(4) and FORM FOR MAINTENANCE OF RECORD IN CASE OF PRENATAL DIAGNOSTIC TEST [PROCEDURE BY GENETIC CLINIC /ULTRASOUND CLINIC/ IMAGING CENTRE SECI'ION A : To be filled in for all Diagnostic Proceduresrrests 1. 2. 3. 4

5. Name and complete address of the Genetic Clinic/ Ultrasound Clinic / Imaging Centre: Registration No.(Under pc & PNDT Act, 1994) .....r..... Patient'sName Age ....,, . Total Number of living children: . (a) Number of living Sons with age of each living son (in years or (b) Number Of living Daughters with age Of each living daughter (in yearsormonths): Husband's/ Wife's/Father's/Mother'sName:

6. Full postal address of the patientwith Contact Number, if any 7.(a) Referred by (Full name and address of Doctor(s)/ Genetic CounsellingCentre): (Referral slips to be preserved carefully with Form F) (b) Self-Referral by Gynaecologist/ Radiologist/ Registered Medical Practitioner conducting the diagnostic procedures: „ (Referral note with indications and case papers Of the patient to be preserved with Form F) (Self-referral does not mean a client coming to a clinic and requesting for the test or the relative/s requesting for the test of a pregnant woman) 8. Last menstrual period or weeks of pregnancy: . SECTION B : To be filled in for preforming non-invasive diagnostic Procedures/Tests only 1 Substituted vide GSR 77(E), dt. 31-1-2014, w.e.f. 4-2-2014. FORM F 52 THE PRE-CONCEPTION AND PRE-NATAL.....RULES 1996 9. Nameofthe doctor performing the procedure/s : (specify 10. Indication/s for

diagnosis procedure with reference to the request made in the referral slip or in a self referral note) (Ultrasonography prenatal diagnosis during pregnancy should only be performed when indicated. The following is the representative list of indications for ultrasound during pregnancy. (Put a "Tick" against the appropriate indication/s for ultrasound) (i) (ii) (iii) (iv) (v) (vi) (vii) (viii) (ix) (x) (xi) (xii) (xiii) (xiv) (xv) (xvi) (Wii) (xviii) (xix) (XX) (xxi) (xxii) (xxiii) To diagnose intra-uterine and/or ectopic pregnancy and confirm viability. Estimation of gestational age (dating) Detection of number of foetuses and their chorionicity. Suspected pregnancy with IUCD in-situ or suspected pregnancy following contraceptive failure / MTP failure. Vaginal bleeding / leaking. Follow-up of cases of abortion. Assessment of cervical canal and diameter of internal os. Discrepancy between uterine size and period of amenorrhea. Any suspected adenexal or uterine pathology / abnormality. Detection of chromosomal abnormalities, fetal structural defects and other abnormalities and their follow-up. TO evaluate fetal presentation and position. Assessment of liquor amnii. Preterm labor / preterm premature rupture of membranes. Evaluation of placental position, thickness, grading and abnormalities (placenta praevia, retro placental hemorrhage, abnormal adherence etc.) Evaluation of umbilical cord - presentation, insertion, nuchal encirclement, number of vessels and presence of true knot. Evaluation of previous Caesarean Section scars. Evaluation of foetal growth parameters, foetal weight and foetal well Color flow mapping and duplex Doppler studies. Ultrasound guided procedures such as medical termination Of pregnancy, external cephalic version etc. and their follow-up. Adjunct to diagnostic and therapeutic invasive interventions such as chorionic villus sampling (CVS), amniocenteses, fetal blood sampling, fetal skin biopsy, amnio-infusion, intrauterine infusion, placement of shunts etc. Observation Of intra-partum events. Medical/ surgical conditions complicating pregnancy. Research/ scientific studies in recognised institutions

11. Procedures carried out (Non-invasive) (Put a "Tick" on the appropriate procedure) (i) Ultrasound (Important Note : Ultrasound is not indicated/advised/performed to determine the sex offoetus except for diagnosis ofsex-!inked diseases such as Duchene Muscular Dystrophy, Hemophilia A & B etc.) (ii) Any other (specify) FORM F 12. 13. 14. 15

16. Date: THE PRE-CONCEIYIION AND PRE-NATAL......RULES 1996 53 Date on which declaration ofpregnant woman/ person was obtained:. Date on which procedures carried out : . Result of the non-invasive procedure carried out (report in brief of the test including ultrasound carried out) The result of pre-natal diagnostic procedures was conveyed to . Any indication for MTP as per the abnormality detected in the diagnostic Name, Signature and Registration Number with Seal of the Gynaecologist / Radiologist / Registered Medical Practitioner performing Diagnostic Procedure / s SECTION C : To be filled for performing invasive Procedures/Tests only 17. Name of the doctor/sperformingtheprocedure/s: 18. History of genetic/medical disease in the family (specify): Basis of diagnosis ("Tick" on appropriate basis of diagnosis): (a) Clinical (b) Bio-chemical (c) Cytogenetic (d) other (e.g. radiological, ultrasonography etc. - specify) 19. Indication/ s for the diagnosis procedure ("Tick" on appropriate indication / s): A. Previous child/ children with; (i) Chromosomal disorders (ii) Metabolic disorders (iii) Congenital anomaly (iv) Mental Disability (v) Haemoglobinopathy (vi) Sex linked disorders (vii) Single gene disorder (viii) Any other (specify) B. Advanced maternal age (35 years) C. Mother [father/ sibling has genetic disease (specify) D. Other(specify) 20. Date on which consentofpregnantwoman/personwas obtained in Form G prescribed inPC & PNDT Act, 1994: .....,,.....

21. Invasive procedures carried out ("Tick" on appropriate indication/s) (i) Amniocentesis (iii) Foetal biopsy (v) Any Other (specify) (ii) Chorionic Villi aspiration (iv) Cordocentesis 22. Any complication/s of invasiveprocedure (specify) : 23. Additional tests recommended (Please mention if applicable) (i) Chromosomal studies (ii) Biochemical studies (iii) Molecular studies (iv) Pre-implantation gender diagnosis (v) Any other (specify) 24. Result of the Procedures/ Tests carried out (report in brief of the invasive tests/ procedurescarriedout) .....,,..

25. Date on which procedures carried out: .54 THE PRECONCEPTION AND PRE-NATAL.....RULES 1996 Relation (if any) : Address & Contact No. :. FORM G 26. The result of pre-natal diagnostic procedures was conveyed to —

27. Any indication for MTP as per the abnormality detected in the diagnostic procedures/tests...... ..... Date: Place: SECTION D : 1, Mrs./Mr. . undergoing . Name, Signature and Registration Number With Seal of the Gynaecologist/ Radiologist/

Registered Medical Practitioner performing Diagnostic Procedure/s Declaration DECLARATION OF THE PERSON UNDERGOING PRENATAL DIAGNOSTIC TEST / PROCEDURE declare that by Prenatal Diagnostic Test/ Procedure. I do not want to know the sex of my foetus. Date Signature/ Thumb impression of the person undergoing the Prenatal Diagnostic Test/ Procedure In Case of thumb Impression Identified by (Name) „ Age Signature of a person attesting thumb impression : — Dated DECLARATION OF DOCTOR/PERSON CONDUCr1NG PRE NATAL DIAGNOSTIC PROCEDURE/TEST „ . (name of the person conducting ultrasonography /image scanning) declare that while conducting ultrasonography / image scanning on M/s./Mr. ..... (name of the pregnant woman or the person undergoing pre natal diagnostic procedure/test), I have neither detected nor disclosed the sex of her foetus to anybody in any manner. Date : Signature. Name in Capitals, Registration Number with Seal of the Gynaecologist / Radiologist / Registered Medical Practitioner Conducting Diagnostic procedure] 1 [FORM G [Refer rule IO] CONSENT (For invasive techniques) wife / daugher of .....yearsresidingat..... .....hereby state that I have been explained fully the probable side effects and after effects of the pre-natal diagnostic procedures. I wish to undergo the preimplantation/pre-natal diagnostic technique/ test/procedures in my own interest to find out the possibility of any abnormality (i.e. disease/deformity / disorder) in the child I am carrying. 1 Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. FORM H THE PRE-CONCEPIION AND PRE-NATAL.....RULES 1996 55 I undertake not to terminate the pregnancy if the pre-natal procedure/ technique/test conducted show the absence Of disease/ deformity/ disorder. I understand that the sex of the foetus will not be disclosed to me. I understand that breach of this undertaking will make me liable to penalty as prescribed in the iPre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994)1 and rules framed thereunder. Date : Signature of the pregnant woman. Place : I have explained the contents of the above to the patient and her companion (Name Relationshlp Date : Address Name, Signature and / Registration Number of Gynaecologist / Medical Geneticist / Radiologist/ Paediatrician/Director of the Clinic / Centre/Laboratory Name, Address and Registration number Of Genetic Clinic / Institu te SEAL] 2[FORM H [Refer rule MAINTENANCE OF PERMANENT RECORD OF APPLICATIONS FOR GRANT / REJECr10N OF REGISTRATION UNDER THE PRE-NATAL 1. 2. 3. 4. 5. 6. 7. 8. 9. IO

11. DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) ACT, 19943 Sl. No. 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* / Ultrasound Clinic* / Imaging Centre*. Date of consideration by Advisory Committee and recommendation Of Advisory Committee, in summary. Outcome Of application (state granted /rejected and date of issue of orders - record date of issue of order in Form B or Form C). Registration number allotted and date of expiry of registration. Renewals (date of renewal and renewed upto). File number in which renewals dealt. Additional information, if any. Name, Designation and Signature of Appropriate Au thority 1 2 3 Now "The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (57 of 1994)". Substituted vide GSR 109(E), dt. 14-2-2003, w.e.f. 14-2-2003. NOW "THE PRECONCEPTION AND PRE-NATAL DIAGNOSTIC TECHNIQUES (PROHIBITION OF SEX SELECTION) ACT, 1994." 56 THE PRE-CONCEPTION AND PRE-NATAL.....RULES 1996 Guidance for Appropriate Authority FORM H (a) (b) (c) (d) (e) (f) (g) Note : Form H is a permanent record to be maintained as a register, in the custody of the Appropriate Authority. *Vleans strike out whichever is not applicable. On renewal, the Registration Number of the Genetic Counselling Centre [Genetic Laboratory / Genetic Clinic / Ultrasound Clinic / Imaging Centre will not change. A fresh registration Number will be allotted in the event of change of ownership or management. Registration number shall not be allotted twice. Each Genetic Counselling Centre/ Genetic Laboratory /Genetic Clinic/ Ultrasound Clinic/ Imaging Centre may be allotted a folio consisting of two pages of the Register for recording Form H. 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. Every folio (i.e. pages) of the Register shall be authenticated by signature of the Appropriate Authority with date, and every subsequent entry shall also be similarly authenticated.] The Principal Notification was published in the Gazette of India vide NO. GSR I(E), dt. 1-1-1996 and last amended vide Noti. No. GSR 60(E), dt. 28-1-2015.