

The Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996

UNION OF INDIA

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The Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996

Rule

THE-PRE-CONCEPTION-AND-PRE-NATAL-DIAGNOSTIC-TECHNIQUES of 1996

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The Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996 Published vide Notification Gazette of India, Extraordinary, Part 2, Section 3(i), dated 1.1.1996

19.

/869 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)] [Now see the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994.], the Central Government hereby makes the following rules, namely:-

1. Short title and commencement.

(1) These rules may be called [The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection)] [Substituted 'Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse)' by G.S.R. 109(E), dated 14.2.2003 (w.e.f. 14.2.2003).] Rules, 1996. (2) They shall come into force on the date of their publication in the Official Gazette.

2. Definitions.

- In these rules, unless the context otherwise requires:- (a) "Act" means The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994); (b) "employee" means a person working in or employed by a Genetic Counselling Centre, a Genetic Laboratory or a Genetic

Clinic, and includes those working on part-time, contractual, consultancy, honorary or on any other basis;(c)"Form" means a Form appended to these rules;[* * *] [Clause (d) omitted by G.S.R. 109(E), dated 14.2.2003 (w.e.f. 14.2.2003).](e)"section" means a section of the Act;(f)words and expressions used herein and not defined in these rules but defined in the Act, shall have the meanings, respectively, assigned to them in the Act.(g)["Mobile Medical Unit" means a mobile vehicle which provides specialised facilities for the patients, requiring basic specialist services and provides improved access to health care facilities and equitable distribution of health services at the doorsteps, across the country especially in the underserved areas. [Inserted by Notification No. G.S.R. 80 (E) dated 7.2.2012 (w.e.f. 1.1.1996)](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.]

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.- [Substituted by G.S.R. 109(E), dated 14.2.2003 (w.e.f. 14.2.2003).](1)Any person being or employing(i)a gynaecologist or a paediatrician having six months experience or four weeks training in genetic counseling, or(ii)a medical geneticists, having adequate space and educational charts/models/equipments for carrying out genetic counselling may set up a genetic counselling center and get it registered as a genetic counselling center.(2)(a)Any person having adequate space and being or employing(i)a Medical Geneticist and(ii)a laboratory technician, having a B.Sc. degree in Biological Sciences or a degree or diploma in medical laboratory course with at least one year experience in conducting appropriate 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.(4)Incubator and oven.(5)Carbon dioxide incubator or closed system with 5% CO₂ atmosphere.(6)Autoclave.(7)Refrigerator.(8)Water bath.(9)Centrifuge.(10)Vortex mixer.(11)Magnetic stirrer.(12)pH Meter.(13)A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.(14)Double distillation apparatus (glass).(15)Such other equipments as may be necessary.(ii)Biochemical studies:(Requirements according to tests to be carried out)(1)Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.(2)Inverted microscope.(3)Incubator and oven.(4)Carbon dioxide incubator or closed system with 5% CO₂ atmosphere.(5)Autoclave.(6)Refrigerator.(7)Water bath.(8)Centrifuge.(9)Electrophoresis apparatus and power supply.(10)Chromatography chamber.(11)Spectro-photometer and Elisa reader or Radio-immunoassay system (with gamma betacounter) or fluorometer for various biochemical tests.(12)Vortex mixer.(13)Magnetic stirrer.(14)pH meter.(15)A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.(16)Double distillation apparatus (glass).(17)Liquid nitrogen tank.(18)Such other equipments as may be necessary.(iii)Molecular studies:(1)Inverted microscope.(2)Incubator.(3)Oven.(4)Autoclave.(5)Refrigerators (4 degree and minus 20 degree

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

(3)(1) Any person having adequate space and being or employing (a)Gynaecologist having experience of performing at least 20 procedures in chorionic villi aspirations per vagina or per abdomen, chorionic villi biopsy, amniocentesis, cordocentesis foetoscopy, foetal skin or organ biopsy or foetal blood sampling, etc., under supervision of an experienced gynaecologist in these fields, or (b)[a sonologist or 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; or"] (c)A medical geneticist, may set up a genetic clinic/ultrasound clinic/imaging centre.

(2)The Genetic Clinic/ultrasound clinic/imaging centre should have or acquire such of the following equipments, as may be necessary for carrying out the tests or procedures-(a)Equipment and accessories necessary for carrying out clinical examination by an obstetrician or gynaecologist.(b)An ultra-sonography machine including mobile ultrasound machine, imaging machine or any other equipment capable of conducting foetal ultrasonography.(c)Appropriate catheters and equipment for carrying out chorionic villi aspirations per vagina or per abdomen.(d)Appropriate sterile needles for amniocentesis or cordocentesis.(e)A suitable foetoscope with appropriate accessories for foetoscopy, foetal skin or organ biopsy or foetal blood sampling shall be optional.(f)Equipment for dry and wet sterilization.(g)Equipment for carrying out emergency procedures such as evacuation of uterus or resuscitation in case of need.(h)Genetic Works Station.](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.] [Inserted by Notification No. GSR 418 (E) dated 4.6.2012 (w.e.f. 1.1.1996)]

[3-A. Sale of ultrasound machines/imaging machines. [Inserted by G.S.R. 109(E) dated 14.2.2003 (w.e.f. 14.2.2003).](1)No organization including a commercial organization or a person, including manufacturer, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment, capable of detecting sex of foetus, shall sell distribute, supply, rent, allow or authorize the use of any such machine or equipment in any manner, whether on payment or otherwise, to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person unless such Centre, Laboratory, Clinic, body or person is registered under the Act.(2)The provider of such machine/equipment to any person/body registered under the Act shall send to the concerned State/UT Appropriate Authority and to the Central Government, once in three months a list of those to whom the machine/equipment has been provided.(3)Any organization or person, including manufacturer, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment capable of detecting sex of foetus selling, distributing, supplying or authorizing, in any manner, the use of any such machine or equipment to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person registered under the Act shall take an affidavit from the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person

purchasing or getting authorization for using such machine/equipment that the machine/equipment shall not be used for detection of sex of foetus or selection of sex before or after conception.][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) Ante natal check up and related services; (b) Referral for complicated pregnancies; (c) Promotion of institutional deliveries; (d) Post-natal check up; (e) Immunization clinics; (f) Treatment of common childhood illness; (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 times 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, on 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.]

4. Registration of [Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres] [Substituted by G.S.R. 109(E), dated 14.2.2003 (w.e.f. 14.2.2003)].

- [(1) An application for registration shall be made to the Appropriate Authority, in duplicate, in Form A, duly accompanied by an Affidavit containing- [Substituted by G.S.R. 109(E), dated 14.2.2003 (w.e.f. 14.2.2003)]. (i) an undertaking to the effect that the Genetic Centre/Laboratory/Clinic/Ultrasound Clinic/Imaging Centre/Combination thereof, as the case may be, shall not conduct any test or procedure, by whatever name called, for selection of sex before or after conception or for detection of sex of foetus except for diseases specified in section 4(2) nor shall the sex of foetus be disclosed to any body; and (ii) an undertaking to the effect that the Genetic Centre/Laboratory/Clinic/Combination thereof, as the case may be, shall display prominently a notice that they do not conduct any technique, test or procedure, etc., by whatever name called, for

detection of sex of foetus or for selection of sex before or after conception.](iii)[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.] [Inserted by Notification No. G.S.R. 80 (E) dated 7.2.2012 (w.e.f. 1.1.1996)](2)The Appropriate Authority, or any person in his office authorised in this behalf, shall acknowledge receipt of the application for registration, in the acknowledgement slip provided at the bottom of Form A, immediately if delivered at the office of the Appropriate Authority, or not later than the next working day if received by post.

5. [Application fee. [Substituted by G.S.R. 109(E), dated 14.2.2003 (w.e.f. 14.2.2003).]

(1)Every application for registration under rule 4 shall be accompanied by an application fee of:-(a)[rupees twenty five thousand] for Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre.(b)[rupees thirty five thousand] [Substituted for the words "Rs. 4,000.00" by Notification No. GSR 418 (E) dated 4.6.2012 (w.e.f. 1.1.1996)] 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 rejected by the Appropriate Authority, no fee shall be required to be paid on re-submission of the application by the applicant for the same body within 90 days of rejection. Provided further that any subsequent application shall be accompanied with the prescribed fee. Application fee once paid will not be refunded.[Provided further that no government institution which provides health and medical services shall be required to pay fee for registration and renewal of registration] [Inserted by Notification No. G.S.R. 599(E), dated 19.6.2017 (w.e.f. 1.1.1996).](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.] [Inserted by Notification No. G.S.R. 80 (E) dated 7.2.2012 (w.e.f. 1.1.1996)]

6. Certificate of registration.

(1)The Appropriate Authority shall, after making such enquiry and after satisfying itself that the applicant has complied with all the requirements, place the application before the Advisory Committee for its advice.(2)Having regard to the advice of the Advisory Committee the Appropriate Authority shall grant a certificate of registration, in duplicate, in Form B to the applicant. One copy of the certificate of registration shall be displayed by the registered Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic at a conspicuous place at its place of business:Provided that the Appropriate Authority may grant a certificate of registration to a Genetic Laboratory or a Genetic

Clinic to conduct one or more specified pre-natal diagnostic tests or procedures, depending on the availability of place, equipment and qualified employees, and standards maintained by such laboratory or clinic.(2)[A (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;(II)the number of portable machines installed and being used in the vehicle;(III)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;(2)B 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.(2)C In case of a breakdown of the vehicle or 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 Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, shall, be carried out only after due notice is given to the applicant by the Appropriate Authority.(5)Grant of certificate of registration or rejection of application for registration shall be communicated to the applicant as specified in Form B or Form C, as the case may be, within a period of ninety days from the date of receipt of application for registration.(6)The certificate of registration shall be non-transferable. In the event of change of ownership or change of management or on ceasing to function as a Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, both copies of the certificate of registration shall be surrendered to the Appropriate Authority.(7)In the event of change of ownership or change of management of the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, the new owner or manager of such Centre, Laboratory or Clinic shall apply afresh for grant of certificate of registration.

7. Validity of registration.

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

8. Renewal of registration.

(1)An application for renewal of certificate of registration shall be made in duplicate in Form A, to the Appropriate Authority thirty days before the date of expiry of the certificate of registration. Acknowledgement of receipt of such application shall be issued by the Appropriate Authority in the manner specified in sub-rule (2) of rule 4.(2)The Appropriate Authority shall, after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of the Act and these rules and having regard to the advice of the advisory Committee in this behalf, renew the certificate of registration, as specified in Form B, for a further period of five years from the date of expiry of the certificate of registration earlier granted.(3)If, after enquiry and after giving an opportunity of being heard to the applicant and having regard to the advice of the Advisory

Committee, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of the Act and these rules, it shall, for reasons to be recorded in writing, reject the application for renewal of certificate of registration and communicate such rejection to the applicant as specified in Form C.(4)The fees payable for renewal of certificate registration shall be one half of the fees provided in sub-rule (1) of rule 5.(5)On receipt of the renewed certificate of registration in duplicate or on receipt of communication or rejection of application for renewal, both copies of the earlier certificate or registration shall be surrendered immediately to the Appropriate Authority by the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic.(6)In the event of failure of the Appropriate Authority to renew the certificate of registration or to communicate rejection of application for renewal of registration within a period of ninety days from the date of receipt of application for renewal of registration, the certificate of registration shall be deemed to have been renewed.

9. Maintenance and preservation of records.

- [(1) Every Genetic Counselling Centre, Genetic Laboratory, [Genetic Clinic including a Mobile Genetic Clinic] [Substituted by G.S.R. 109(E), dated 14.2.2003 (w.e.f. 14.2.2003).], Ultrasound Clinic and Imaging Centres shall maintain a register showing, in serial order, the names and addresses of the men or women given genetic counselling, subjected to pre-natal diagnostic procedures or pre-natal diagnostic tests, the names of their spouse or father and the date on which they first reported for such counselling, procedure or test.] [Inserted by Notification No. G.S.R. 80 (E) dated 7.2.2012 (w.e.f. 1.1.1996)](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 man or woman subjected to any pre-natal diagnostic procedure/technique/test, shall be as specified in Form E.] [Substituted by G.S.R. 109(E), dated 14.2.2003 (w.e.f. 14.2.2003).](4)[The record to be maintained by every [Genetic Clinic including a Mobile Genetic Clinic] [Substituted by G.S.R. 109(E), dated 14.2.2003 (w.e.f. 14.2.2003).], 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 a permanent records.(6)All case-related records, forms of consent, laboratory results, microscopic pictures, sonographic plates or slides, recommendations and letters shall be preserved by the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic for a period of two years from the date of completion of counselling, pre-natal diagnostic procedure or pre-natal diagnostic test, as the case may be. In the event of any legal proceedings, the records shall be preserved till the final disposal of legal proceedings, or till the expiry of the said period of two years, whichever is later.(7)In case the Genetic Counselling Centre or Genetic Laboratory of Genetic Clinic maintains records on computer or other electronic equipment a printed copy of the record shall be taken and preserved after authentication by a person responsible for such record.(8)[Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres shall send a complete report in respect of all pre-conception or pregnancy related procedures/techniques/tests conducted by them in respect of each month by 5th day of the following month to the concerned Appropriate Authority.] [Inserted by G.S.R. 109(E) dated

14.2.2003 (w.e.f. 14.2.2003).]

10. Conditions for conducting pre-natal diagnostic procedures.

- [(1) Before conducting preimplantation genetic diagnosis, or any pre-natal diagnostic technique/test/procedure such as amniocentesis, chorionic villi biopsy, foetoscopy, foetal skin or organ biopsy or cordocentesis, a written consent, as specified in Form G, in a language the person undergoing such procedure understands, shall be obtained from her/him.] [Substituted by G.S.R. 109(E), dated 14.2.2003 (w.e.f. 14.2.2003).][(1-A) 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.] [Inserted by G.S.R. 109(E) dated 14.2.2003 (w.e.f. 14.2.2003).](2) All the State Governments and Union territories may issue translation of Form G in languages used in the State or Union territory and where no official translation in a language understood by the pregnant woman is available, the Genetic Clinic may translate Form G into a language she understands.

11. [Facilities for inspection. [Substituted by G.S.R. 109(E), dated 14.2.2003 (w.e.f. 14.2.2003).]

(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 organization if the organization has not got itself registered under the Act. These machines of such organizations shall be confiscated and further action shall be taken as per the provisions of the Section 23 of the Act.]

12. Procedure for search and seizure.

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

may furnish evidence of commission of an offence punishable under the Act. Explanation .-In these rules-(1)"Genetic Laboratory/Genetic Clinic/Genetic Counselling Centre" would include an ultrasound centre/imaging centre/nursing home/hospital/institute or any other place, by whatever name called, where any of the machines or equipments capable of selection of sex before or after conception or performing any procedure technique or test for pre-natal detection of sex of foetus, is used;(2)"material object" would include records, machines and equipments; and(3)"seize" and "seizure" would include "seal" and "sealing" respectively.](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 authorized 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 [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] [Substituted for the words "within a period of thirty days of such change" by Notification No. GSR 418 (E) dated 4.6.2012 (w.e.f. 1.1.1996)].

14. Conditions for analysis or test and pre-natal diagnostic procedures.

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

15. Meetings of the advisory Committees.

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

16. Allowances to members of the Central Supervisory Board.

(1) The ex officio members, and other Central and State Government officers appointed to the Board will be entitled to Travelling allowance and Daily Allowance for attending the meetings of the Board as per the Travelling 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 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, Genetic Clinic, Ultrasound Clinic and Imaging Centres] [Substituted by G.S.R. 109(E), dated 14.2.2003 (w.e.f. 14.2.2003).] 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, Genetic Clinic, Ultrasound Clinic and Imaging Centres] [Substituted by G.S.R. 109(E), dated 14.2.2003 (w.e.f. 14.2.2003).], and shall be made available to the clientele on demand for perusal. (3) The Appropriate Authority, the Central Government, the State Government, and the Government/Administration of the Union Territory may publish periodically lists of registered [Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinic and Imaging Centres] [Substituted by G.S.R. 109(E), dated 14.2.2003 (w.e.f. 14.2.2003).] 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.

18. [[Inserted by G.S.R. 109(E) dated 14.2.2003 (w.e.f. 14.2.2003).]

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

18A. [Code of Conduct to be observed by Appropriate Authorities. [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014]

(1)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] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](ii)[observe and implement the provisions of the Act and Rules in a balanced and standardised manner in the course of their work] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](iii)[conduct their work in a just manner without any bias or a perceived presumption of guilt] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](iv)[refrain from making any comments which demean individuals on the basis of gender, race, religion] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](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] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](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:-] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](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] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](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] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](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] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](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] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](v)[conduct frequent meetings of the Advisory Committee to expedite the decisions regarding renewal, cancellation and suspension of registration] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014][(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:-] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](i)[maintain appropriate diaries in support of registration of each of the complaint or case under the Act] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](ii)[attend to all complaints and maintain transparency in the follow-up action of the complaints] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](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] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](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)] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014][(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:-] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](i)[dispose of the application for renewal and new registration within a period of seventy days from the date of receipt of application] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](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.] [Inserted by Notification No. G.S.R. 60 (E) dated 28.1.2015][(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:-] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](i)[ensure that protection and expenses of witness shall be met from the registration amount collected] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](ii)[ensure that all the notifications of the Government be produced in original in the court and a copy of the same be preserved] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](iii)[ensure that while filing the cases, all the papers, records, statements, evidence,panchnama and other material objects attached to the case file shall be in original] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](iv)[suspend the certificate of registration in the course of taking legal action of seizure and sealing of the facility] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](v)[ensure that there shall be no violation of the provisions of the Medical Termination Pregnancy Act, 1971 (34 of 1971) and the Rules made there-under while implementing the provisions of the Pre-conception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](vi)[take immediate action for filing appeal, revision or other proceeding in 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] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014][(6) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall submit quarterly progress report to the Government of India through State Government and maintain Form H for keeping the information of all the registrations made readily available] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014][(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 equipments, namely:-] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](i)[monitor the sales and import of ultrasound machines including portable or buyback, assembled, gift, scrap or demo] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](ii)[ensue regular quarterly reports from ultrasound manufacturers, dealers, wholesalers and retailers and any person dealing with the sales of ultrasound machines at the State level] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](iii)[conduct periodical survey and audit of all the ultrasound machines sold and operating in the State or district to identify the unregistered machines] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](iv)[file complaint against any owner of the unregistered ultrasound machine and against the seller of the unregistered ultrasound machine] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014][(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:-] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](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] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](ii)[place all the inspection reports once in three months before the Advisory Committee for follow up action] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](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] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](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] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](b)[procure the certified copy of the order of conviction as soon as possible and in the case of conviction of the 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] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014][(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:-] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](i)[obtain prior sanction or approval of the Government of India for any resolution concerning the implementation of the provisions of the Act] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](ii)[take action, if any, required under the Act and immediately on receipt of notice under clause (b) of subsection (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] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014][(10) All the Appropriate Authorities including the State, District and Sub-district notified under the Act, inter-alia, shall follow the following financial guidance, namely:-] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](i)[maintain a separate and independent bank account operated by two officers jointly, at all levels] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014](ii)[ensure transparency and adherence to standard Government financial norms for disbursement of money] [Inserted by Notification No. G.S.R. 119 (E) dated 24.2.2014]

19. Appeals.

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

19A. [The manner for filing and disposal of the appeal under clause (i) and (ii) of section 21 of the Act. [Inserted by Notification No. G.S.R. 492 (E), dated 22.5.2017 (w.e.f. 1.1.1996).]

(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)The Central Appellate Authority shall consist of an officer not below the rank of the Union territory Appropriate Authority.(2)(a)The State Government may, by notification in the Official Gazette, 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 shall -(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(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)The 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)service by the appellant; or(b)by hand delivery (dasti); or(c)by registered post with acknowledgement due; or(d)by electronic mail or fax.(8)(a)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 email or courier at the address mentioned in the appeal.(b)The appellant may present in person or through his duly authorised legal representative, at the time of hearing of the appeal.(c)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:(d)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.(e)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].

I

[***] [Omitted by G.S.R. 109(E), dated 14-2-2003 (w.e.f. 14-2-2003)]

II

[***] [Omitted by G.S.R. 109(E), dated 14-2-2003 (w.e.f. 14-2-2003)]

III

[***] [Omitted by G.S.R. 109(E), dated 14-2-2003 (w.e.f. 14-2-2003)][Form A] [Substituted by G.S.R. 109(E), dated 14-2-2003 (w.e.f. 14-2-2003)][See rules 4(1) and 8(1)](To be submitted in Duplicate with supporting documents as enclosures)Form of Application for Registration or Renewal of Registration of a Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre

1. Name of the applicant

(Indicate name of the organisation sought to be registered)

2. Address of the applicant

3. Type of facility to be registered

(Please specify whether the application is for registration of a Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre or any combination of these)

4. Full name and address/addresses of Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre with Telephone/Fax number(s) Telegraphic/Telex/E-mail address(s).

5. Type of ownership of Organisation

(individual ownership/partnership/company/co-operative/any other to be specified). In case type of organization is other than individual ownership, furnish copy of articles of association and

names and addresses of other persons responsible for management, as enclosure.

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

7. Specific pre-natal diagnostic procedures/tests for which approval is sought

(a) Invasive (i) amniocentesis/chorionic villi aspiration/chromosomal/biochemical/molecular studies (b) Non-Invasive Ultrasonography

Leave blank if registration is sought for Genetic Counselling Centre only.

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

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

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

(i) Ultrasound

(ii) Amniocentesis

(iii) Chorionic villi aspiration

(iv) Foetoscopy

(v) Foetal biopsy

(vi) Cordocentesis

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

(i) Chromosomal studies

(ii) Biochemical studies

(iii) Molecular studies

(iv) Preimplantation genetic diagnosis

10. Names, qualifications, experience and registration number of employees (may be furnished as an enclosure).

11. State whether the Genetic Counselling Centre/ Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre* qualifies for registration in terms of requirements laid down in Rule 3.]

12. For renewal applications only:

(a) Registration No.

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

13. List of Enclosures:

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

Date: (.....) Place Name, designation and signature of the person authorized to sign on behalf of the organisation to be registered. *Strike out whichever is not applicable or not necessary. All enclosures are to be authenticated by signature of the applicant. Declaration I, Sh./Smt./Kum./Dr son/daughter/wife of aged years resident of working as (indicate designation) in (indicate name of the organisation to be registered)

..... hereby declare that I have read and understood the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994) and the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996. I also undertake to explain the said Act and Rules to all employees of the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre in respect of which registration is sought and to ensure that Act and Rules are fully complied with. Date: (.....) Place Name, designation and signature of the person authorized to sign on behalf of the organisation to be registered. [SEAL OF THE ORGANISATION SOUGHT TO BE REGISTERED] Acknowledgement [See rules 4(2) and 8(1)] The application in Form A in duplicate for grant*/renewal* of registration of Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*/Ultrasound Clinic*/Imaging Centre* by (Name and address of applicant) has been received by the Appropriate Authority On (date). *The list of enclosures attached to the application in Form A has been verified with the enclosures submitted and found to be correct. OR *On verification it is found that the following documents mentioned in the list of enclosures are not actually enclosed. This acknowledgement does not confer any rights on the applicant for grant or renewal of registration. (.....) Signature and Designation of Appropriate Authority, or authorised person in the Office of the Appropriate Authority. Date: Place: SEAL Original/duplicate For Display* FORM B [See rules 6(2), 6(5) and 8(2)] Certificate of Registration (To be issued in duplicate)

1. In exercise of the powers conferred under section 19(1) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994) the Appropriate Authority hereby grants registration to the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*/Ultrasound Clinic*/Imaging Centre* named below for purposes of carrying out Genetic Counselling/Pre-natal Diagnostic Procedures*/Pre-natal Diagnostic Tests/ultrasonography under the aforesaid Act for a period of five years ending on

2. This registration is granted subject to the aforesaid Act and Rules thereunder and any contravention thereof shall result in suspension or cancellation of this Certificate of Registration before the expiry of the said period of five years apart from prosecution.

A. Name and address of the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*/Ultrasound Clinic*/Imaging Centre*.

B. Pre-natal diagnostic procedures* approved for
(Genetic Clinic).

Non-Invasive

(i) Ultrasound

Invasive

- (ii) Amniocentesis
- (iii) Chorionic villi biopsy
- (iv) Foetoscopy
- (v) Foetal skin or organ biopsy
- (vi) Cordocentesis
- (vii) Any other (specify)

C. Pre-natal diagnostic tests* approved (for Genetic Laboratory)

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

D. Any other purpose (please specify)

3. Model and make of equipments being used (any change is to be intimated to the Appropriate Authority under rule 13).

4. Registration No.allotted

5. Period of validity of earlier Certificate of Registration.

(For renewed Certificate of Registration only)

FromTo.....Signature, name and designation ofThe Appropriate AuthoritySEAL*Strike out whichever is not applicable or not necessary.Display one copy of this certificate at a conspicuous place at the place of business.FORM C[See rules 6(3), 6(5) and 8(3)]Form for Rejection of Application for Grant/renewal of RegistrationIn exercise of the powers conferred under section 19(2) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 the Appropriate Authority hereby rejects the application for grant*/renewal* of registration of the undermentioned Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*/Ultrasound Clinic*/Imaging Centre*.(1)Name and address of the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*/Ultrasound Clinic*/Imaging Centre*(2)Reasons for rejection of application for grant/renewal of registration :Signature, name and designation of the Appropriate Authority with Seal of officeDate:Place:FORM D[See rule 9(2)]Form for Maintenance of Records by the Genetic Counselling Centre

1. Name and address of Genetic Counselling centre.

2. Registration No.

3. Patient's name

4. Age

5. Husband's/Father's name

6. Full address with Tel. No., if any

7. Referred by (Full name and address of Doctor(s) with registration No.(s) (Referral note to be preserved carefully with case papers)

8. Last menstrual period/weeks of pregnancy

9. History of genetic/medical disease in the family (specify)

Basis of diagnosis : (a) Clinical (b) Bio-chemical (c) Cytogenetic (d) Other (e.g. radiological, ultrasonography)

10. Indication for pre-natal diagnosis

A. Previous child/children with: (i) Chromosomal disorders (ii) Metabolic disorders* Strike out whichever is not applicable or necessary. (iii) Congenital anomaly (iv) Mental retardation (v) Haemoglobinopathy (vi) Sex linked disorders (vii) Single gene disorder (viii) Any other (specify) B. Advanced maternal age (35 years or above) C. Mother/father/sibling having genetic disease (specify) D. Others (specify)

11. Procedure advised*

(i) Ultrasound (ii) Amniocentesis (iii) Chorionic villi biopsy (iv) Foetoscopy (v) Foetal skin or organ biopsy (vi) Cordocentesis (vii) Any other (specify)

12. Laboratory tests to be carried out

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

13. Result of diagnosis

If abnormal give details. Normal/Abnormal

14. Was MTP advised ?

15. Name and address of Genetic Clinic* to which patient is referred.

16. Dates of commencement and completion of genetic counselling.

Name, Signature and Registration No. of the Medical Geneticist/Gynaecologist/Paediatrician administering Genetic Counselling Place: Date: FORM E [See rule 9(3)] Form for Maintenance of

Records by Genetic Laboratory

1. Name and address of Genetic Laboratory

2. Registration No.

3. Patient's name

4. Age

5. Husband's/Father's name

*Strike out whichever is not applicable or necessary.

6. Full address with Tel. No., if any

**7. Referred by/sample sent by (full name and address of Genetic Clinic)
(Referral note to be preserved carefully with case papers)**

**8. Type of sample: Maternal blood/Chorionic villus sample/amniotic
fluid/Foetal blood or other foetal tissue (specify)**

9. Specify indication for pre-natal diagnosis

A. Previous child/children with (i) Chromosomal disorders (ii) Metabolic disorders (iii) Malformation(s) (iv) Mental retardation (v) Hereditary haemolytic anaemia (vi) Sex linked disorder (vii) Single gene disorder (viii) Any other (specify) B. Advanced maternal age (35 years or above) C. Mother/father/sibling having genetic disease (specify) D. Other (specify)

10. Laboratory tests carried out (give details)

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

11. Result of diagnosis

If abnormal give details. Normal/Abnormal

12. Date(s) on which tests carried out.

The results of the Pre-natal diagnostic tests were conveyed to

on.....Name, Signature and Registration No. of the Medical Geneticist/Director of the Institute
Place: Date: FORM F [See proviso to section 4(3), rule 9(4) and rule 10(1-A)] Form for Maintenance of Record in Respect of Pregnant Woman by Genetic Clinic/Ultrasound Clinic/Imaging Centre

1. Name and address of the Genetic Clinic/Ultrasound Clinic/Imaging Centre.

2. Registration No.

3. Patient's name and her age

4. Number of children with sex of each child

5. Husband's/Father's name

6. Full address with Tel. No., if any

7. Referred by (full name and address of Doctor(s)/Genetic Counselling Centre (Referral note to be preserved carefully with case papers)/self referral

8. Last menstrual period/weeks of pregnancy

9. History of genetic/medical disease in the family (specify)

Basis of diagnosis: (a) Clinical (b) Bio-chemical (c) Cytogenetic (d) Other (e.g. radiological, ultrasonography, etc., (specify)

10. Indication for pre-natal diagnosis

A. Previous child/children with: (i) Chromosomal disorders (ii) Metabolic disorders (iii) Congenital anomaly (iv) Mental retardation (v) Haemoglobinopathy (vi) Sex linked disorders (vii) Single gene disorder (viii) Any other (specify) B. Advanced maternal age (35 years) C. Mother/father/sibling has genetic disease (specify) D. Other (specify)

11. Procedures carried out (with name and registration No. of Gynaecologist/Radiologist/Registered Medical Practitioner) who performed it.

Non-Invasive (i) Ultrasound (specify purpose for which ultrasound is to be done during pregnancy) [List of indications for ultrasonography of pregnant women are given in the note below] Invasive (ii) Amniocentesis (iii) Chorionic Villi aspiration (iv) Foetal biopsy (v) Cordocentesis (vi) Any other (specify)

12. Any complication of procedure-please specify

13. Laboratory tests recommended*

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

14. Result of

(a)pre-natal diagnostic procedure (give details)(b)Ultrasonography(specify abnormality detected, if any). Normal/Abnormal

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

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

**17. The result of pre-natal diagnostic procedure were conveyed to
.....on.....**

18. Was MTP advised/conducted?

19. Date on which MTP carried out.

Date:Place:Name, Signature and Registration number of theGynaecologist/Radiologist/Director of the ClinicDeclaration of Pregnant WomanI, Ms.(name of the pregnant woman) declare that by undergoing ultrasonography/image scanning, etc. I do not want to know the sex of my foetus.Signature/Thumb impression of pregnant womanDeclaration of Doctor/Person Conducting Ultrasonography/Image ScanningI. (name of the person conducting ultrasonography/image scanning) declare that while conducting ultrasonography/image scanning on Ms (name of the pregnant woman), I have neither detected no disclosed the sex of her foetus to any body in any manner.Name and signature of the person conducting ultrasonography/image scanning/Director or owner of genetic clinic/ultrasound clinic imaging centre.Important Note :(i)Ultrasound is not indicated/advised/performed to determine the sex of foetus except for diagnosis of sex-linked diseases such as Duchenne Muscular Dystrophy, Haemophilia A & B, etc.(ii)During pregnancy Ultrasonography should only be performed when indicated. The following is the representative list of indications for ultrasound during pregnancy.(1)To diagnose intra-uterine and/or ectopic pregnancy and confirm viability.(2)Estimation of gestational age (dating).(3)Detection of number of foetuses and their chorionicity.(4)Suspected pregnancy with IUCD in-situ or suspected pregnancy following contraceptive failure/MTP failure.(5)Vaginal bleeding/leaking.(6)Follow-up of cases of abortion.(7)Assessment of cervical canal and diameter of internal os.*Strike out whichever is not applicable or not necessary.(8)Discrepancy between uterine size and period of amenorrhoea.(9)Any

suspected adenexal or uterine pathology/abnormality.(10)Detection of chromosomal abnormalities, foetal structural defects and other abnormalities and their follow-up.(11)To evaluate foetal presentation and position.(12)Assessment of liquor amnii.(13)Preterm labour/preterm premature reapture of membranes.(14)Evaluation of placental position, thickness, grading and abnormalities (placenta praevia, retroplacental position, thickness, grading and abnormalities (placenta praevia, retroplacental haemorrhage, abnormal adherence, etc.).(15)Evaluation of umbilical cord-presentation, insertion, nuchal encirclement, number of vessels and presence of true knot.(16)Evaluation of previous Caesarean Section scars.(17)Evaluation of foetal growth parameters, foetal weight and foetal well being.(18)Colour flow mapping and duplex Doppler studies.(19)Ultrasound guided procedures such as medical termination of pregnancy, external cephalic version, etc., and their follow-up.(20)Adjunct to diagnostic and therapeutic invasive interventions such as chorionic villus sampling (CVS), amniocenteses, foetal blood sampling, foetal skin biopsy, amnio infusion, intrauterine infusion, placement of shunts, etc.(21)Observation of intra-partum events.(22)Medical/surgical conditions complicating pregnancy.(23)Research/scientific studies in recognised institutions.

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

FORM G[See rule 10]Form of Consent(For invasive techniques)I.

..... wife/daughter of Age years
residing at hereby state that I have been explained fully the probable side effects and after effects of the pre-natal diagnostic procedures.I wish to undergo the preimplantation/pre-natal diagnostic technique/test/procedures in my own interest to find out the possibility of any abnormality (i.e., disease/deformity/disorder) in the child I am carrying.I undertake not to terminate the pregnancy if the pre-natal procedure/technique/test conducted show the absence of disease/deformity/disorder.I understand that the sex of the foetus will not be disclosed to me.I understand that breach of this undertaking will make me liable to penalty as prescribed in the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994) and rules framed thereunder.

Date:Place:Signature of the pregnant woman.I have explained the contents of the above to the patient and her companion (Name Address Relationship) in a language she/they understand.

DateName, Signature and/Registration number of Gynaecologist/Medical Geneticist/Radiologist/Paediatrician/Director of the Clinic/Centre/LaboratoryName, Address and Registration number of Genetic Clinic/Institute

SEALFORM H[See rule 9(5)]Form for Maintenance of Permanent Record of Applications for Grant/Rejection of Registration Under the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse Act, 1994

1. Sl. No.

2. File number of Appropriate Authority.

3. Date of receipt of application for grant of registration.

4. Name, Address, Phone/Fax, etc., of Applicant:

5. Name and address(es) of Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*/Ultrasound Clinic*/Imaging Centre*.

6. Date of consideration by Advisory Committee and recommendation of Advisory Committee, in summary.

7. Outcome of application (state granted/rejected and state of issue of orders-record date of issue of order in Form B or Form C).

8. Registration number allotted and date of expiry of registration.

9. Renewals (date of renewal and renewed upto).

10. File number in which renewals dealt.

11. Additional information, if any.

Name, Designation and Signature of Appropriate Authority

Guidance for Appropriate Authority(a)Form H is a permanent record to be maintained as a register, in the custody of the Appropriate Authority.(b)*Means strike out whichever is not applicable.(c)On renewal, the Registration Number of the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/Ultrasound Clinic/Imaging Centre will not change. A fresh registration Number will be allotted in the event of change of ownership or management.(d)Registration number shall not be allotted twice.(e)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.(f)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.(g)Every folio (i.e. 2 pages) of the Register shall be authenticated by signature of the Appropriate Authority with date, and every subsequent entry shall also be similarly authenticated.[Form-I [Inserted by Notification No. G.S.R. 492 (E), dated 22.5.2017 (w.e.f. 1.1.1996).][See rule 19(a)]Before The Central Appellate Authority or the State Appellate Authority Appeal No. /20.....In The Matter of:-Name and Address of the AuthorityAppellateName and Address of The Authority Whose Order is ChallengedRespondentMost respectfully showeth:The above mentioned appellant appeals against the order passed by the, concerned Appropriate Authority at (Name of place and address) against the appellant in (details of the case if any) dated and sets forth the following grounds of objection of the order appealed :-

1. Particulars of the order including number of order, if any, against which the appeal is preferred

2. Brief facts of the case

3. Findings of the Appropriate Authority challenged

4. Grounds of appeal

5. Copy of the order enclosed along with all the documents relied upon by the Appellant

6. Any other information/documents in support of appeal

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 in favour of the appellant. Signature of the Appellant Place Date Verification: I, 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 Form - J[See rule 19A(4)(b)] Proforma Affidavit Before the Central Appellate Authority or the State Appellate Authority In the matter of : Name of the Appellant Appellant Versus Concerned Appropriate Authority Respondent Affidavit I, S/o-D/o aged R/o do hereby solemnly declare as under :

1. That I am 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. Deponent Appendix - A[See Rule 19A(4)(c)] Before The Central Appellate Authority or The State Appellate Authority In the matter of : Name of The Appellant Appellant Versus Concerned Appropriate

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Signature of the AppellantSynopsis

Date Particulars of events

Signature of the AppellantList of Documents

S. NO PARTICULARS PAGES

Signature of the Appellant]