

## **Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996**

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**No. G.S.R. 1 :-** In exercise of the powers conferred by Section 32 of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1997), 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) Rules, 1996.

(2) They shall come into force on the date of their publication in the Official Gazette.

**2. Definitions :-** In these rules, unless the context otherwise requires:-

(a) "Act" means The Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994);

(b) "Employee" means a person working in or employed by a Genetic Counselling Centre, a Genetic Laboratory or a Genetic Clinic, and includes those working on part-time, contractual, consultancy, honorary or on any other basis;

(c) "Form" means a Form appended to these rules;

(d) \*[ \* \* \* ]

*\* omitted by G.S.R.109(E), dated 14.2.2003 (w.e.f.14.2.2003). "(d) "Schedule" means a schedule appended to these rules;"*

(e) "Section" means a section of the Act;

(f) Words and expressions used herein and not defined in these rules but defined in the Act, shall have the meanings, respectively, assigned to them in the Act.

**3. Minimum requirements :-** 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 :-

(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 geneticist, having adequate space and educational charts/models/equipments for carrying out genetic counseling may set up a genetic counseling center and get it registered as a genetic counseling 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% CO<sub>2</sub> atmosphere.
- (6) Autoclave.
- (7) Refrigerator.
- (8) Water bath.
- (9) Centrifuge.
- (10) Vortex mixer.
- (11) Magnetic stirrer.
- (12) pH meter.
- (13) A sensitive balance (preferable 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% CO<sub>2</sub> atmosphere.
- (5) Autoclave.
- (6) Refrigerator.
- (7) Water bath.
- (8) Centrifuge.
- (9) Electrophoresis apparatus and power supply.
- (10) Chromatography chamber.
- (11) Spectro-photometer and Elisa reader or Radio-immunoassay system (with gamma betacounter) or fluorometer for various biochemical test.
- (12) Vortex mixer.
- (13) Magnetic stirrer.
- (14) pH meter.
- (15) A sensitive balance (preferable electronic) with sensitivity of 0.1 milligram.
- (16) Double distillation apparatus (glass).
- (17) Liquid nitrogen tank.
- (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) Vortex mixer.
- (10) Magnetic stirrer.
- (11) pH meter.
- (12) A sensitive balance (preferable 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, Imaging Specialist, Radiologist or Registered Medical Practitioner having Post Graduate degree or diploma or six months training or one year experience in sonography or image scanning, or

(c) A medical geneticist

May set up a genetic clinic/ultrasound clinic/imaging center.

(2) The Genetic Clinic/ultrasound clinic/imaging center 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 foetoscopy 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.

**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, 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 such 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.

**4. Registration of Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic :-** (1) 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; 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.

(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.

**5. Application Fee :-** (1) Every application for registration under rule 4 shall be accompanied by an application fee of:-

(a) Rs.3000.00 for Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre.

(b) Rs.4000.00 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 that any subsequent application 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 head quarters of the Appropriate Authority concerned. The fees collected by the Appropriate Authority 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 to the applicant. One copy of the certificate of registration shall be displayed by the registered Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or 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, Ultrasound Clinic or Imaging Centre to conduct one or more specified pre-natal diagnostic tests or procedures, depending on the availability of place, equipment and qualified employees, and standards maintained by such laboratory or clinic.

(3) If, after enquiry and after giving an opportunity of being heard to the applicant and having regard to the advice of the Advisory Committee, the Appropriate Authority is satisfied that the applicant has not complied with the requirements of the Act and these

rules, it shall, for the reasons to be recorded in writing, reject the application for registration and communicate such rejection to the applicant as specified in Form C.

(4) An enquiry under sub-rule(1), including inspection at the premises of the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or 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 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, Genetic Clinic, Ultrasound Clinic or 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 Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging 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 certificate of registration shall be surrendered immediately to the Appropriate Authority by the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or 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 :-** (1) Every Genetic Counselling Centre, Genetic Laboratory, 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 counseling, subjected to pre-natal diagnostic procedures or pre-natal diagnostic tests, the names of their spouses or fathers and the date on which they first reported for such counseling, procedure or test.

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

(3) The record to be maintained by every Genetic Laboratory, in respect of each 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 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 Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre for a period of two years from the date of completion of counseling, prenatal 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, Genetic Clinic, 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.

(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.

**10. Conditions for conducting pre-natal diagnostic procedures :-** (1) Before conducting pre-implantation genetic diagnosis, or any pre-natal diagnostic technique/test/procedure such as amniocentesis, chorionic villi biopsy, 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.

(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 anybody. 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 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 :-** (1) Every Genetic Counselling Centre, Genetic Laboratory and 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 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 authorized 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 therefore 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.

(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 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 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-

(1) 'Genetic Laboratory/Genetic Clinic/Genetic Counselling Centre' would include an ultrasound center/imaging center/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, Genetic Clinic, Ultrasound Clinic or Imaging Centre 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 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 Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or 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 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 Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or 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 arrangement, by way of mounting a guard or sealing of the premises of the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic Ultrasound Clinic or 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 Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre shall intimate every change of employee, place, address and equipment installed, to the Appropriate Authority within a period of thirty days of such change.

**14. Conditions for analysis or test and pre-natal 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 ultrasonography 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 Allowance rules applicable to them.

(2) The non-official members appointed to, and Members of Parliament elected to the Board will be entitled to Travelling Allowance and Daily Allowance for attending the meetings of the Board as admissible to non-official 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 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 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 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 Genetic Counselling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics and Imaging Centres 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. 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 person 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 prenatal diagnostic techniques/procedures 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/the 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 the Rules which are punishable offences;

(vii). help the law enforcing agencies in bringing to book the violators of the provisions of the Act and the 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.

**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.

\*CHEDULE I

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SCHEDULE II

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SCHEDULE III

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*\* Omitted by G.S.R.109(E), dated 14.2.2003 (w.e.f.14.2.2003)*

## FORM A

[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 addresses)
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 (Government 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) CordocentesisWhether 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  
authorised to sign on behalf of the  
organisation to be registered

DECLARATION

I, Shri/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) Rules, 1996.

I also undertake to explain the said Act and rules to all employees of the 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 authorised 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 authorized 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)  
From .....To.....

Signature, name and designation of the Appropriate Authority

Seal

Date :

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  
REGISTRATION**

In exercise of the powers conferred under Section 19(2) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994, the Appropriate Authority ..... hereby rejects the application for grant\*/renewal\* of registration of the 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 Office

Date:

Place:

\* Strike out whichever is not applicable or necessary .

**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
    - (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 diagnosis

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
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 villas 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. Others (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 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<sup>3</sup>

(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

Normal/Abnormal

(Specify abnormality detected, if any)

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:

Name, Signature and Registration No. of

Place:

the Gynaecologist/Radiologist/Director of the Clinic

**DECLARATION OF PREGNANT WOMAN**

I, 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.

Signaturer/Thumb impression of pregnant woman

**DECLARATION OF DOCTOR/PERSON CONDUCTING  
ULTRASONOGRAPHY /IMAGE SCANNING**

I, (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 nor 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 and 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.
  - (8) Discrepancy between uterine size and period of amenorrhoea.
  - (9) Any suspected adnexal 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 rupture of membranes.
  - (14) Evaluation of placental 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 (CYS), 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:

Signature of the pregnant woman

Place:

I have explained the contents of the above to the patient and her companion  
(Name.....Address.....Relationship .....

.....) in a language she/they understand .

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/Institute

Seal :

Date :

**FORM 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 date 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 up to.
10. File number in which renewals dealt
11. Additional information, if any

Name, Designation and Signature of Appropriate Authority

\_\_\_\_\_

\* \* \* \* \*