

THE PRE-NATAL DIAGNOSTIC TECHNIQUES (REGULATION AND PREVENTION OF MISUSE) RULES, 1996

1. Short title and commencement.- (1) These rules may be called the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996.

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

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) “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.- (1) The minimum qualifications of the employees, the minimum equipment and minimum place for a Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic shall be as specified in Schedules I, II and III.

(2) Where an institute, hospital, nursing home, or any place, by whatever name called, provides services jointly of Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic, or any combination of these, it shall conform to the requirements as specified in Schedules I, II and III.

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.

(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.2000.00 for Genetic Counselling Centre;

(b) Rs.3000.00 for Genetic Laboratory;

(c) Rs.3000.00 for Genetic Clinic; and

- (d) Rs.4000.00 for an institute, hospital, nursing home, or any place providing jointly the services of a Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic or any combination of such Centre, Laboratory or Clinic.

(2) The application fee shall be paid by a demand draft drawn in favour of the Appropriate Authority, on any scheduled bank located at the headquarters of the Appropriate Authority.

6. Certificate of 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.

(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 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 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 and Genetic Clinic shall maintain a register showing, in serial order, the names and addresses of the women given genetic counseling, subjected to pre-natal diagnostic procedures or pre-natal diagnostic tests, the names of their husbands or fathers and the date on which they first reported for such counseling, procedure or test.

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

(3) The record to be maintained by every Genetic Laboratory, in respect of each woman subjected to any pre-natal diagnostic test, shall be as specified in Form E.

(4) The record to be maintained by every Genetic Clinic, in respect of each woman subjected to any pre-natal diagnostic procedure, shall be as specified in Form F.

(5) The Appropriate Authority shall maintain a permanent record of applications for grant or renewal of certificate of registration as specified in Form H. Letters of intimation of every change of employee, place, address and equipment installed shall also be preserved as permanent records.

(6) All case related records, forms of consent, laboratory results, microscopic pictures, sonographic plates or slides, recommendations and letters shall be preserved by the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic for a period of two years from the date of completion of counseling, pre-natal diagnostic procedure or pre-natal diagnostic test, as the case may be. In the event of any legal proceedings, the records shall be preserved till the final disposal of legal proceedings, or till the expiry of the said period of two years, whichever is later.

(7) In case the Genetic Counselling Centre or Genetic Laboratory or Genetic Clinic maintains 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.

10. Conditions for conducting pre-natal diagnostic procedures.- (1) Before conducting any pre-natal diagnostic procedure, a written consent, as specified in Form G, in a language the pregnant woman understands, shall be taken from her:

Provided that where a Genetic Clinic has taken a sample of any body tissue or body fluid and sent it to a Genetic Laboratory for analysis or test, it shall not be necessary for the Genetic Laboratory to obtain a fresh consent in Form G.

(2) All the State Governments and Union Territories may issue translation of Form G in languages used in the State or Union Territory and where no official translation in a language understood by the pregnant woman is available, the Genetic Clinic may translate Form G into a language she understands.

11. Facilities for inspection.- Every Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic shall afford reasonable facilities for inspection of the place, equipment and records to the Appropriate Authority or to any other person authorized by the Appropriate Authority in this behalf.

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 or Genetic Clinic, in the presence of two or more independent and respectable persons for the purposes of Section 30.

(2) A list of any document, record, register, book, pamphlet, advertisement or any other material object found in the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic and seized shall be prepared in duplicate at the place of effecting the seizure. Both copies of such list shall be signed on every page by the Appropriate Authority or the officer 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 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 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 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, 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 arrangement, by way of mounting a guard or sealing of the premises of the Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, for safe keeping, listing and removal of documents, records, book or any other material object to be seized, and to prevent any tampering with such documents, records, books or any other material object.

13. Intimation of changes in employees, place or equipment. – Every Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic shall intimate every change of employee, place, address and equipment installed, to the Appropriate Authority within a period of thirty days of such change.

14. Conditions for analysis or test and pre-natal 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 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 and Genetic Clinic shall prominently display on its premises a notice in English and in the local language or languages for the information of the public, to effect that disclosure of the sex of the foetus is prohibited under law.

(2) At least one copy each of the Act and these rules shall be available on the premises of every Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic, and shall be made available to the 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 and Genetic Clinics and findings from the reports and other information in their possession, for the information of the public and for use by the experts in the field.

SCHEDULE I

[See Rule 3 (1)]

REQUIREMENTS FOR REGISTRATION OF A GENETIC COUNSELLING CENTRE

A.PLACE

A room with an area of seven (7) square meters.

B.EQUIPMENT

Educational charts/models.

C. EMPLOYEES

Any one of the following-

- (1) Medical Geneticist.**
- (2) Gynaecologist with 6 months' experience, in genetic counseling, or having completed 4 weeks' training in genetic counseling.**
- (3) Paediatrician with 6 months' experience in genetic counseling, or having completed 4 weeks' training in genetic counseling.**

SCHEDULE II

See Rule 3(1)]

REQUIREMENTS FOR REGISTRATION OF A GENETIC LABORATORY

A. PLACE

A room with adequate space for carrying out tests.

B.EQUIPMENT

These are categorized separately for each of the under-mentioned studies.

Chromosomal studies:

- (1) Laminar flow-hood with ultraviolet and fluorescent light or other suitable culture hood.**
- (2) Photo-microscope with fluorescent source of light.**
- (3) Inverted microscope.**
- (4) Incubator 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 (preferable electronic) with sensitivity of 0.1 milligram.
- (14) Double distillation apparatus (glass).

Biochemical studies:

(requirements according to tests to be carried out)

- (1) Laminar flow-hood with ultraviolet and fluorescent light or other suitable culture hood.
 - (2) Inverted microscope.
 - (3) 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 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.

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.

C.EMPLOYEES

(1) A Medical Geneticist.

(2) A laboratory technician having a B.Sc. degree in Biological Sciences or a degree or a diploma in medical laboratory course with at least one year's experience in conducting appropriate pre-natal diagnostic tests.

SCHEDULE III

[See Rule 3(1)]

REQUIREMENTS FOR REGISTRATION OF A GENETIC CLINIC

A.PLACE

A room with an area of twenty (20) square metres with appropriate aseptic arrangements.

B.EQUIPMENT

(1) Equipment and accessories necessary for carrying out clinical examination by an obstetrician/gynaecologist.

(2) Equipment, accessories necessary for other facilities required for operations envisaged in the Act.

(a) An ultra-sonography machine.*

(b) Appropriate catheters and equipment for carrying out chorionic villi aspirations per vagina or per abdomen.*

(c) Appropriate sterile needles for amniocentesis or cordocentesis.*

(d) A suitable foetoscope with appropriate accessories for foetoscopy, foetal skin or organ biopsy or foetal blood sampling shall be optional.

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

(3) Equipment for dry and wet sterilization.

(4) Equipment for carrying out emergency procedures such as evacuation of uterus or resuscitation in case of need.

C.EMPLOYEES

(1) A gynaecologist with adequate experience in pre-natal diagnostic procedures (should have performed at least 20 procedures under supervision of a gynaecologist experienced in the procedure which is going to be carried out, for example chorionic villi biopsy, amniocentesis, cordocentesis and others indicated at B above).

(2) A Radiologist or Registered Medical Practitioner for carrying out ultrasonography. The required experience shall be 100 cases under supervision of a similarly qualified person experienced in these techniques.

FORM A

[See rules 4(1) and 8(1)]

(To be submitted in Duplicate)

WITH SUPPORTING DOCUMENTS AS ENCLOSURES, ALSO IN DUPLICATE FORM OF APPLICATION FOR REGISTRATION OR RENEWAL OF REGISTRATION OF A GENETIC COUNSELLING CENTRE/GENETIC LABORATORY/GENETIC CLINIC

1.Name of the applicant

(specify Sh./Smt./Kur./Dr.)

2.Address of the applicant

3.Capacity in which applying

(specify owner/partner/managing director/other-to be stated)

4.Type of facility to be registered

(specify Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic/any combination of these)

5.Full name and address/addresses of Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic with Telephone/Telegraphic Telex/Fax E-mail numbers.

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

7.Type of Institution (Govt. Hospital/Municipal Hospital/Public Hospital/Private Hospital/Private Nursing Home/Private Clinic/Private Laboratory/any other to be stated.) 8.Specific pre-natal diagnostic procedures/tests for which approval is sought (for example amniocentesis, chorionic villi aspiration/chromosomal/biochemical/molecular studies etc.)

Leave blank if registration sought for Genetic Counselling Centre only.

9.(a) Space available for the Counselling Centre/Clinic/Laboratory give total work area excluding lobbies, waiting rooms, stairs etc. and enclose plan)

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

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

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

- (i) Ultrasound
- (ii) Amniocentesis
- (iii) Chorionic villi aspiration
- (iv) Foetoscopy
- (v) Foetal biopsy
- (vi) Cordocentesis

(b) Whether facilities are available in the Laboratory, Clinic for the following:

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

12. Names, qualifications, experience and registration number of employees may be furnished as an enclosure (Refer Schedules I, II or III).

13. State whether the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic[1] qualifies for registration in terms of minimum requirements laid down in Schedule I, II and III and if not, reasons therefore.

14. For renewal applications only:

- (a) Registration No.
- (b) Date of issue and date of expiry of existing certificate of registration.

15. List of Enclosures:

Please attach a list of enclosures giving the supporting documents enclosed to this application.

Date:

(.....)

Place

Name and signature of applicant

DECLARATION

I, Sh./Smt./Kum./Dr..... son/daughter/wife of aged
..... years resident of

..... 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, 1995,

2.1 also undertake to explain the said Act and Rules to all employees of the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic in respect of which registration is sought and to ensure that Act and Rules are fully complied with.

Date:

(.....)

Place

Name and signature of applicant

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* 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:

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* named below for purposes of carrying out Genetic Counselling/Pre-natal Diagnostic Procedures*/Pre-natal Diagnostic Tests as defined in the aforesaid Act for a period of five years ending on**
 - 2. This registration is granted subject to the aforesaid Act and Rules thereunder and any contravention thereof shall result in suspension or cancellation of this Certificate of Registration before the expiry of the said period of five years.**
- A. Name and address of the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*.**
 - B. Name of Applicant for registration.**
 - C. Pre-natal diagnostic procedures approved for (Genetic Clinic).**
 - (i) Ultrasound**
 - (ii) Amniocentesis**
 - (iii) Chorionic villi biopsy**
 - (iv) Foetoscopy**
 - (v) Foetal skin or organ biopsy**
 - (vi) Cordocentesis**
 - (vii) Any other (specify)**
 - D. Pre-natal diagnostic tests* approved (for Genetic Laboratory)**
 - (i) Chromosomal studies**

(ii) Biochemical studies

(iii) Molecular studies

3. Registration No. allotted

4. For renewed Certificate of Registration only

Period of validity of earlier Certificate From To Or Registration.

Signature, name and designation of

The Appropriate Authority

Date:

SEAL

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)]

REJECTION OF APPLICATION FOR REGISTRATION OR 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 Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic* named below for the reasons stated.

Name and address of the Genetic Counselling Centre*/Genetic

Laboratory*/Genetic Clinic*

Name of Applicant who has applied for registration

Reasons for rejection of application for registration

Signature, name and designation of

The Appropriate Authority

Date:

SEAL

***Strike out whichever is not applicable or necessary.**

FORM D

[See rule 9(2)]

NAME, ADDRESS AND REGISTRATION No. OF GENETIC COUNSELLING CENTRE RECORD TO BE MAINTAINED BY THE GENETIC COUNSELLING CENTRE

1. Patient's name

2. Age

3. Husband's/Father's name

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

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

6. Last menstrual period/weeks of pregnancy

7. History of genetic/medical disease in the family (specify) Basis of diagnosis:

(a) Clinical

(b) Bio-chemical

(c) Cytogenetic

(d) Other (e.g. radiological)

8. 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) Any other (specify)

B. Advanced maternal age (35 years)

C. Mother/father/sibling has genetic disease (specify)

D. Others (specify)

9. Procedure advised^[2]

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

10. Laboratory tests to be carried out

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

11. Result of pre-natal diagnosis

If abnormal give details.

Normal/Abnormal

12. Was MTP advised?

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

14. Dates of commencement and completion of genetic counseling.

**Name, Signature and Registration No. of the
Medical Geneticist/Gynaecologist/Paediatrician**

Date:

FORM E

[See Rule 9(3)]

**NAME, ADDRESS AND REGISTRATION No. OF GENETIC LABORATORY RECORD TO BE
MAINTAINED BY THE GENETIC LABORATORY**

1. Patient's name

2. Age

3. Husband's/Father's name

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

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

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

7. 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) Any other (specify)

B. Advanced maternal age (-35 years)

C. Mother/father/sibling has genetic disease (specify)

D. Other (specify)

8. Laboratory tests carried out (give details)

- (viii) Chromosomal studies
- (ix) Biochemical studies
- (x) Molecular studies

9. Result of pre-natal diagnosis

If abnormal give details.

Normal/Abnormal

10. 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**

Date:

FORM F

[See Rule 9(4)]

NAME, ADDRESS AND REGISTRATION No. OF GENETIC CLINIC

RECORD TO BE MAINTAINED BY THE GENETIC CLINIC

1. Patient's name

2. Age

3. Husband's/Father's name

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

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

6. Last menstrual period/weeks of pregnancy

7. History of genetic/medical disease in the family (specify) Basis of diagnosis:

(a) Clinical

(b) Bio-chemical

(c) Cytogenetic

(d) Other (e.g. radiological-specify)

8. Indication for pre-natal diagnosis

A. Previous child/children with:

(i) Chromosomal disorders

(ii) Metabolic disorders

(viii) Congenital anomaly

(ix) Mental retardation

(x) Haemoglobinopathy

(xi) Sex linked disorders

(xii) Any other (specify)

B. Advanced maternal age (35 years)

C. Mother/father/sibling has genetic disease (specify)

D. Other (specify)

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

- (i) Ultrasound**
- (ii) Amniocentesis**
- (iii) Chorionic Villi aspiration**
- (iv) Foetal biopsy**
- (v) Cordocentesis**
- (vi) Any other (specify)**

10. Any complication of procedure – please specify

11. Laboratory tests recommended[3]

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

12. Result of pre-natal diagnostic procedure and specify Normal/Abnormal abnormality detected, if any.

13. Was MTP advised/conducted?

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

15. Date on which MTP carried out.

16. Date on which consent obtained.

17. The result of pre-natal diagnostic procedure were conveyed toon

**Name, Signature and Registration number of the
Gynaecologist/Radiologist/Registered Medical
Practitioner**

Date:

Place

FORM G

[See Rule 10]

FORM OF CONSENT

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 pre-natal diagnostic procedures in my interest to find out the possibility of any abnormality (i.e. deformity or disorder) in the child I am carrying.

I undertake not to terminate the pregnancy if the pre-natal procedure and any pre-natal tests conducted show the absence of deformity or disorders. I understand that the sex of the foetus will not be disclosed to me.

I understand that breach of this undertaking will make me liable to penalty as prescribed in the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994).

Date

Signature

Place

I have explained the contents of the above consent to the patient and her companion (Name Address Relationship) in a language she/they understand.

Name, Signature and/Registration number

Of Gynaecologist

Date

Name, Address and Registration number of

Genetic Clinic

FORM H

[See Rule 9(5)]

**PERMANENT RECORD OF APPLICATION FOR REGISTRATION, GRANT OF REGISTRATION
REJECTION OF APPLICATION FOR REGISTRATION AND RENEWALS OF REGISTRATION**

1.SI. 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*.

6.Date on which case considered by Advisory Committee and recommendation of Advisory Committee, in summary.

7.Outcome of application (state granted/rejected and date of issue of orders).

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)Against item 7, record date of issue of order in Form B or Form C.

(d)On renewal, the Registration Number of the Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic will not change. A fresh registration Number will be allotted in the event of change of ownership or management.

(e)No registration number shall be allotted twice.

(f)Each Genetic Counselling Centre/Genetic Laboratory/Genetic Clinic may be allotted a folio consisting of two facing pages of the Register for recording Form H.

(g)The space provided for 'additional information' may be used for recording suspension, cancellations, rejection of application for renewal, change of ownership/management, outcome of any legal proceedings, etc.

(h)Every folio (i.e. 2 pages) of the Register shall be authenticated by signature of the Appropriate Authority with date, and every subsequent entry shall also be similarly authenticated.

The Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Rules, 2003.

G.S.R.109(E).- In exercise of the powers conferred by section 32 of the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994), the Central Government hereby makes the following amendments to the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996.

1. (1) These may be called the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Rules, 2003.

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

2. In the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996 (hereinafter referred to as the said rules) in rule 1, for sub-rule (1) the following sub-rule shall be substituted, namely:-

“(1) These Rules may be called the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996.”

3. In the said rules, in rule 2, clause (d) shall be omitted.

4. In the said rules, for rule 3 the following rule shall be substituted, namely:-

“3. The qualifications of the employees, the requirement of equipment etc. for a Genetic Counseling 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 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 prenatal 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 beta-counter) 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, 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 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.”.

5. In the said rules, after rule 3 a new rule 3A shall be inserted as follows, namely:-

“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 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.”.

6. In the said rules, in rule 4 for sub-rule (1) the following sub-rule shall be substituted, namely:-

“(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.”.

7. In the said rules, for rule 5, the following rule shall be substituted, namely:-

“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 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.”.

8. In the said rules, in rule 9, -

(a) for sub-rule (1), the following sub-rule shall be substituted, namely:-

“(1) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, 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.”;

(b) for sub-rule (3), the following sub-rule shall be substituted, namely:-

“(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.”;

(c) for sub-rule (4), the following sub-rule shall be substituted, namely:-

“(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.”;

(d) after sub-rule (7), the following sub-rule shall be inserted, namely:-

“(8) Every Genetic Counseling 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.”.

9. In the said rules, in rule 10, -

(a) for sub-rule (1), the following sub-rule shall be substituted, namely:-

“(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.”;

(b) after sub-rule (1), the following new sub-rule (1A) shall be inserted, namely:-

“(1A) Any person conducting ultrasonography/image scanning on a pregnant woman shall give a declaration on each report on ultrasonography/image scanning that he/she has neither detected nor disclosed the sex of foetus of the pregnant woman to any body. The pregnant woman shall before undergoing ultrasonography/image scanning declare that she does not want to know the sex of her foetus.”.

10. In the said rules, for rule 11, the following rule shall be substituted, namely:-

“11. Facilities for inspection.- (1) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre, nursing home, hospital, institute or any other place where any of the machines or equipments capable of performing any procedure, technique or test capable of pre-natal determination of sex or selection of sex before or after conception is used, shall afford all reasonable facilities for inspection of the place, equipment and records to the Appropriate Authority or to any other person authorised by the Appropriate Authority in this behalf for registration of such institutions, by whatever name called, under the Act, or for detection of misuse of such facilities or advertisement 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 authorized by it may seal and seize any ultrasound machine, scanner or any other equipment, capable of detecting sex of foetus, used by any organisation if the organisation has not got itself registered under the Act. These machines of the organisations may be released if such organisation pays penalty equal to five times of the registration fee to the Appropriate Authority concerned and gives an undertaking that it shall not undertake detection of sex of foetus or selection of sex before or after conception.”.

11. In the said rules, in rule 12 for sub-rule (1), the following sub-rule shall be substituted, namely:-

“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.”.

12. In the said rules, after rule 17, the following rules shall be inserted, namely:-

“18. Code of Conduct to be observed by persons working at Genetic Counseling Centres, Genetic Laboratories, Genetic Clinics, Ultrasound Clinics. Imaging Centres etc.

All persons including the owner, employee or any other persons associated with Genetic Counseling 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 for purposes not covered under section 4(2) of the Act or selection of sex before or after conception, is informed that such procedures lead to violation of the Act and these Rules which are punishable offences;
- (vii) help the law enforcing agencies in 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.

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.”.

13. In the said rules, Schedule I, Schedule II and Schedule III shall be omitted.

14. In the said rules, for the words “Genetic Counselling Centre, Genetic Laboratory and Genetic Clinic”, the words “Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centres” shall be substituted wherever they occur.

15. In the said rules, for Form A, Form B, Form C, Form D, Form E, Form F, Form G, and Form H, the following forms shall be substituted respectively, namely:-

“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 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 [1] 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

authorized to
registered.

Name, designation and signature of the person
sign on behalf of the organisation to be

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 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

Date:

SEAL

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[2]

- (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 counseling.

Name, Signature and Registration No. of the

Geneticist/Gynaecologist/Paediatrician

Medical

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 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)

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^[3]

- (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 toon

18. Was MTP advised/conducted?

19. Date on which MTP carried out.

Date: Name, Signature and Registration number of the

Place 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.

Signature/Thumb impression of pregnant woman

3 Strike out whichever is not applicable or not necessary

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 & 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 fetuses 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 (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.

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

Date

Name, Address and Registration number of

Genetic Clinic/Institute

SEAL

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.SI. 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 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.**
- (e) Registration number shall not be allotted twice.**
- (f) 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.**

(g) The space provided for 'additional information' may be used for recording suspension, cancellations, rejection of application for renewal, change of ownership/management, outcome of any legal proceedings, etc.

(h) Every folio (i.e. 2 pages) of the Register shall be authenticated by signature of the Appropriate Authority with date, and every subsequent entry shall also be similarly authenticated."

(Ms. K. Sujatha Rao)

Joint Secretary to the Government of India.

[No.N.24026/14/2002-PNDT Cell]

Footnote:- The Principal Notification was published in the Gazette of India vide No.G.S.R. 1(E) dated 1st January, 1996.

This is the first amendments to the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996.

[1] Strike out whichever is not applicable or not necessary. All enclosures are to be authenticated by signature of the applicant.

[2] Strike out whichever is not applicable or necessary.