Pre-Conception & Pre-Natal Diagnostic Techniques Act, 1994 - Rules

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

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) XXXX

   (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. 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 counselling or

      (ii) a medical geneticist,

      having adequate space and educational charts/models/equipments for carrying out genetic counselling may set up a genetic counselling centre and get it registered as a genetic counselling centre.

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2. (a) Any person having adequate space and being or employing

(i) a Medical Geneticist and

(ii) a laboratory technician having a B.Sc. degree in Biological Sciences or a degree or diploma in medical laboratory course with at least one year experience in conducting appropriate pre-natal diagnostic techniques, tests or procedures may set up a genetic laboratory.

(b) Such laboratory should have or acquire such of the following equipments as may be necessary for carrying out chromosomal studies, bio-chemical studies and molecular studies:-

(i) Chromosomal studies:

(1) Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.

(2) Photo-microscope with fluorescent source of light.

(3) Inverted microscope.

(4) Incubator and oven.

(5) Carbon-dioxide incubator or closed system with 5% CO2 atmosphere.

(6) Autoclave.

(7) Refrigerator.

(8) Water bath.

(9) Centrifuge.

(10) Vortex mixer.

(11) Magnetic stirrer.

(12) pH meter.

(13) A sensitive balance (preferable electronic) with sensitivity of 0.1 milligram.

(14) Double distillation apparatus (glass).

(15) Such other equipment 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.

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(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 equipment 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

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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 cathethers 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.

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.

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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.

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5. ***Application Fee.-***

1. Every application for registration under rule 4 shall be accompanied by an application fee of:-

(a) Rs.3000 for Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre.

(b) Rs.4000 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 counselling , 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 counselling , 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 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 counselling , pre-natal diagnostic procedure or pre-natal diagnostic test, as the case may be. In the event of any legal proceedings, the records shall be preserved till the final disposal of legal proceedings, or till the expiry of the said period of two years, whichever is later.

7. In case the Genetic Counselling Centre or Genetic Laboratory, Genetic Clinic, Ultrasound Clinic or Imaging Centre maintains records on computer or other electronic equipment, a printed copy

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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 preimplantation 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 any body. The pregnant woman shall before undergoing ultrasonography/image scanning declare that she does not want to know the sex of her foetus.

2. All the State Governments and Union Territories may issue translation of Form G in languages used in the State or Union Territory and where no official translation in 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 authorized 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 the organizations may be released if such organization 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.

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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 centre/imaging centre/nursing home/hospital/institute or any other place, by whatever name called, where any of the machines or equipments capable of selection of sex before or after conception or performing any procedure, technique or test for pre-natal detection of sex of foetus is used;
   2. 'material object' would include records, machines and equipments; and
   3. 'seize' and 'seizure' would include 'seal' and 'sealing' respectively.

2. A list of any document, record, register, book, pamphlet, advertisement or any other material object found in the Genetic Counselling Centre, Genetic Laboratory, 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 ma-

terial 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 ultrasonographic monitoring so as to prevent any damage to the foetus and placenta.

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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 pre-natal 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.

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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 organization 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(es).

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

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

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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

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

      (i) Chromosomal studies

      (ii) Biochemical studies

      (iii)Molecular studies

      (iv)Preimplantation gender 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

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

for registration in terms of requirements laid down in Rule 3.

12. For renewal applications only:
    (a) Registration No.
    (b) Date of issue and date of expiry of existing certificate of registration.

13. List of Enclosures:
    (Please attach a list of enclosures/supporting documents attached to this application.

Date: (……..)

Place Name, designation and signature of the person authorized to sign on behalf of the organization to be registered.

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DECLARATION

I, Sh./Smt./Kum./Dr…….. son/daughter/wife of …….. aged …….. years resident of ……working as (indicate designation) …….. in (indicate name of the organization 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 organization 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.

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(……..)

Signature and Designation of Appropriate Authority, or authorized person in the Office of the Appropriate Authority.

Date:

SEAL

Place:

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.

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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

Display one copy of this certificate at a conspicuous place at the place of business

D. Any other purpose (please specify for ultrasound clinic/imaging centre)

3. Model and make of equipment 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:

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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 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:

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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, 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)

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B. Advanced maternal age (35 years)

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)

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12. Laboratory tests to be carried out

(i) Chromosomal studies

(ii) Biochemical studies

(iii) Molecular studies

(iv) Preimplantation gender diagnosis

13. Result of pre-natal 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 .

Place:
Date:

Name, Signature and Registration No. of the Medical Geneticist/Gynaecologist/Paediatrician administering Genetic Counselling.

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

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 has genetic disease (specify)
   D. Other (specify)

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10. Laboratory tests carried out (give details)

(i) Chromosomal studies

(ii) Biochemical studies

(iii) Molecular studies

(iv) Preimplantation gender 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:

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FORM F

[See Proviso to section 4(3), Rule 9(4) and Rule 10(1A))]

FORM FOR MAINTENANCE OF RECORDS IN CASE OF A PREGNANT WOMAN BY GENETIC CLINIC/ULTRASOUND CLINIC/IMAGING CENTRE

1. Name and address of 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)

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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 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) Pre-implantation gender diagnosis

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14. Result of

(a) pre-natal diagnostic procedure (give details)

(b) Ultrasonography (specify abnormality detected, if any). Normal/Abnormal

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

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

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

18. Was MTP advised/conducted?

19. Date on which MTP carried out.

Name, Signature and Registration number of the Gynaecologist/Radiologist/Director of the Clinic

Date:
Place

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

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/Thump impression of pregnant woman

_____

3. Strike out whichever is not applicable or not necessary

DECLARATION OF DOCTOR/PERSON CONDUCTING ULTRASONOGRAPHY/IMAGE SCANNING

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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 anybody in any manner.

Name and signature of the person conducting ultrasonography/image scanning/Director or owner of genetic clinic/ultrasound clinic/imaging centre.

Important Note:

i. Ultrasound is not indicated/advised/performed to determine the sex of foetus except for diagnosis of sex-linked diseases such as Duchenne Muscular Dystrophy, Haemophilia A & B etc.

ii. During pregnancy Ultrasonography should only be performed when indicated. The following is the representative list of indications for ultrasound during pregnancy.

1. To diagnose intra-uterine and/or ectopic pregnancy and confirm viability.
2. Estimation of gestational age (dating).
3. Detection of number of foetuses and their chorionicity.
4. Suspected pregnancy with IUCD in-situ or suspected pregnancy following contraceptive failure/MTP failure.
5. Vaginal bleeding/leaking.
6. Follow-up of cases of abortion.
7. Assessment of cervical canal and diameter of internalos.

8. Discrepancy between uterine size and period of amenorrhoea.

9. Any suspected adenexal or uterine pathology/abnormality.

10. Detection of chromosomal abnormalities, foetal structural defects and other abnormalities and their follow-up.

11. To evaluate foetal presentation and position.

12. Assessment of liquor amnii.

13. Pre-term labour/pre-term 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 woman shall keep complete record thereof in the clinic/center in Form – F and any deficiency 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.

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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.

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Date

Place

Signature of the pregnant woman.

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

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. 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 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- 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.

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Name, Designation and Signature of
Appropriate Authority

Guidance for Appropriate Authority

(a) Form H is a permanent record to be maintained as a register, in the custody of the Appropriate Authority.

(b)*Means strike out whichever is not applicable.

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

(d) Registration number shall not be allotted twice.

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

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

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

APPENDIX-III

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

G.S.R. 540 (E), dated 26th November, 1996- In exercise of the powers conferred by Sec.32 of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994), the Central Government hereby makes the following rules, namely:-

1. ***Short title and commencement***.-

   1. These rules may be called the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) (Advisory Committees) 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) "Advisory Committee" means an Advisory Committee constituted under sub-section (5) of Section 17 of the Act;

   (c) "Chairman" means the Chairman of the Advisory Committee appointed under sub-section (5) of Section 17;

   (d) "Principle rules" means the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Rules, 1996;

   (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 or in the principal rules, as the case may be, shall have the meanings, respectively, assigned to them in the Act or in the principle rules.

3. ***Terms and conditions of appointment as a member of an Advisory Committee***.- (1) No person shall be appointed as a member of an Advisory Committee if he –

   (a) has been convicted and sentenced to imprisonment for an offence which, in the opinion of the Central Government or the State Government, as the case may be, involves moral turpitude; or

   (b) is an undischarged insolvent; or

   (c) is of unsound mind and stands so declared by a competent Court; or

   (d) has been removed or dismissed from the service of the Government or a Corporation owned or controlled by the Government; or

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(e) has, in the opinion of the Central Government or the State Government, as the case may be, such financial or other interest as is likely to affect prejudicially the discharge by him of his functions as a member of the Advisory Committee; or

(f) has, in the opinion of the Central Government or the State Government, as the case may be, been associated with the sue or promotion of pre-natal diagnostic techniques for determination of sex.

2. Every member of an Advisory Committee shall be a resident of the State or Union Territory, for which the Advisory Committee to which he is appointed as a member, has been constituted.

3. A member of an Advisory Committee shall hold office during the pleasure of the Central Government or the State Government, as the case may be.

4. Subject to the provisions of sub-rule (3), every such member shall hold office for a period not exceeding three years:

   Provided that any person holding office as a member of an Advisory Committee immediately before the commencement of these rules shall hold such office only for the term of three years from the date of his appointment.

5. A retiring member or a member whose term of office has expired by efflux of time shall be eligible for re-appointment.

6. A casual vacancy in an Advisory Committee caused by the resignation, death, transfer or removal of any member or otherwise shall be filled by fresh appointment and the person so appointed shall hold office for a period not exceeding the term of office of the member in whose place he is appointed.

7. The Central Government or the State Government, as the case may be, may remove from office any member of an Advisory Committee before the expiration of his term of office.

8. Every member of an Advisory Committee shall be entitled to draw traveling and daily allowances for journeys performed by him for attending the meetings (including a meeting adjourned for want of quorum), of the Advisory Committee or for the purpose of discharging any other duties prescribed under the Act, or under the Principle rules or under these rules, on the scale admissible to First Grade Officers of the Government of the State or of the Union Territory, as the case may be.

4. ***Meetings of the Advisory Committees***.- The intervening period between any two meetings of an Advisory Committee shall not exceed sixty days.

5. ***Notice of meetings***.-

1. At least seven clear days' notice of all meetings of the Advisory Committee shall be given to each member, but an urgent meeting may be called by the Chairman at three clear days' notice:

   Provided that if the Chairman is not available, and a meeting is required to be held within the time limit prescribed in Rule 4, the Appropriate Authority may call a meeting with seven clear days' notice after consultation with not less than four of the members of the Advisory Committee.

2. The notice shall state the business to be transacted at the meeting and no business other than that stated shall be transacted at such meeting except with the consent of the Chairman or on his motion.

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6. ***Business ordinarily to be transacted at meetings***.- The business of the Advisory Committee shall ordinarily be transacted at a meeting duly called in accordance with the provisions of these rules:

   Provided that the Chairman may, if he thinks fit, circulate any urgent matter among the members of the Advisory Committee for their opinion.

7. ***Quorum***.- At every meeting of the Advisory Committee, four members shall form a quorum.

8. ***Chairman of the meeting***.- Meetings of the Advisory Committee shall be presided over by the Chairman or in his absence, or if no Chairman has been appointed, by a member elected by the members present from among themselves.

9. ***Assistance to be rendered by the Appropriate Authority to the Advisory Committee***.-

   1. Every meeting of the Advisory Committee shall be attended by the Appropriate Authority concerned.
   2. All secretarial and other assistance to the Advisory Committee for the discharge of its functions shall be provided by the Appropriate Authority.
   3. The Appropriate Authority shall issue the notice of meeting, agenda, notes on agenda and the minutes of the meeting, in consultation with the Chairman, subject to the provisions of Rules 5,6, 7 and 12.

10. ***Decisions on questions before the Advisory Committee***.-

    1. The advice tendered by the Advisory Committee shall be adopted, and in the event of any difference of opinion amongst the members, the matter shall be put to vote and decided by a simple majority of the members present.
    2. The Appropriate Authority shall not have a right to vote.
    3. In the event of tie in votes, the Chairman or in his absence, the member presiding shall have a second or casting vote.
    4. The fact of any question having been decided by the process of voting instead of by adoption, shall be recorded in the minutes of that meeting of the Advisory Committee.

11. ***Vacancies etc. not to invalidate proceedings of the Advisory Committees***.- No meeting or proceeding of the Advisory Committee shall be invalid merely by reason of-

    (a) any vacancy in, or any defect in the constitution of the Advisory Committee; or

    (b) any defect in the appointment of a person to be a member of the Advisory Committee; or

    (c) any irregularity in the procedure adopted by the Advisory Committee not affecting the merits of the case.

12. ***Record of proceedings of the Advisory Committee***.- One set of the agenda, notes on agenda, supporting documents and minutes of every meeting of the Advisory Committee shall be authenticated by the signature of the Chairman or in his absence by the signature of the member presiding, and preserved by the Appropriate Authority as permanent records.

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