

# **Jammu and Kashmir Pre-Conception and Pre-Natal Sex Selection/determination (Prohibition and Regulation) Rules, 2006**

JAMMU & KASHMIR

India

## **Jammu and Kashmir Pre-Conception and Pre-Natal Sex Selection/determination (Prohibition and Regulation) Rules, 2006**

### **Act 373 of 2006**

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Jammu and Kashmir Pre-Conception and Pre-Natal Sex Selection/determination (Prohibition and Regulation) Rules, 2006 Published vide SRO 373 of 2006, Dated 07.12.2006, w.e.f. 7.12.2006 Health And Medical Education Department In exercise of the powers conferred by section 32 of the Jammu and Kashmir Preconception and Prenatal Sex Selection/Determination (Prohibition and Regulation) Act, 2002, the Government hereby makes the following rules, namely :

### **1. Short title and commencement**

(1) These rules may be called Jammu and Kashmir Pre-conception and Pre-natal Sex Selection/Determination (Prohibition and Regulation) Rules, 2006. (2) They shall come into force on the date of their publication in the Government Gazette.

### **2. Definitions**

In these rules, unless the context otherwise requires, (a) "Act" means Jammu and Kashmir Preconception and Prenatal Sex Selection /Determination (Prohibition and Regulation) Act 2002. (b) "Employee" means a person working in or employed by a Genetic Laboratory or a Genetic Clinic or an Ultrasound' Clinic or an Imaging Centre and includes those working on part time, contractual, honorary or on any other basis ; (c) "Form" means a Form appended to these rules ; (d) "Section" means a section of the Act. (e) Words and expressions used in these rules but not defined herein shall have the meanings as assigned to them in the Act.

### **3. Qualification of the employee, the requirement of equipment etc. for a genetic counselling centre, genetic laboratory, genetic clinic ultrasound clinic and imaging centre**

(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 after getting it registered.(2)Any person having adequate space of not less then 500 sft and being or employing. (i)A Medical Geneticist and(ii)A Laboratory Technician having a B.Sc. degree in Biological Sciences 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, which shall have the following equipments for carrying out chromosomal studies, biochemical studies and molecular studies;(a)Chromosomal studies(1)Laminar flow hood with ultraviolet and fluorescent light or other suitable culture hood.(2)Photo microscope with fluorescent source of light.(3)Inverted microscope.(4)Incubator and oven.(5)Carbon dioxide incubator or closed system with 5% CO<sub>2</sub> atmosphere.(6)Autoclave.(7)Refrigerator.(8)Water bath.(9)Centrifuge.(10)Vortex mixer.(11)Magnetic stirrer.(12)Positive Hydrogen-ion (PH) meter.(13)A sensitive balance (preferably electronic) with sensitivity of 0.1 milligram.(14)Double distillation apparatus (glass) ;any(15)Any such other equipment as may be necessary.(b)Biochemical studies (requirements according to tests to be carried out):(1)Laminar flow hood with ultraviolet and fluorescent light or others suitable culture hood.(2)Inverted microscope.(3)Incubator and oven.(4)Carbon dioxide incubator closed system with 5% CO<sub>2</sub> atmosphere.(5)Autoclave.(6)Refrigerator.(7)Water bath.(8)Centrifuge.(9)Electrophoresis apparatus and power supply.(10)Chromatography chamber.(11)Spectrophotometer and Elisa reader or Radio immunoassay system (with gamma beta counter) or fluorometer for various biochemical tests.(12)Vortex mixer.(13)Magnetic stirrer.(14)Positive Hydrogen-ion (PH) meter.(15)A sensitive balance (preferably electronic) with sensitivity of 0.1 milligramme.(16)Double distillation apparatus (glass).(17)Liquid nitrogen tank(18)Any such other equipments as may be necessary.(c)Molecular studies:(1)Inverted microscope.(2)Incubator.(3)Oven.(4)Autoclave.(5)Refrigerator (4 degree and minus 20 degree centigrade).(6)Water bath.(7)Micro centrifuge.(8)Electrophoresis apparatus and power supply.(9)Vortex mixer.(10)Magnetic stirrer.(11)Positive Hydrogen-ion (PH) meter.(12)A sensitive balance (preferably electronic) with sensitivity of 0.1 milligramme.(13)Double distillation apparatus (glass).(14)Polymerase Chain Reaction (P.C.R.) machine(15)Refrigerator centrifuge.(16)Refrigerator centrifuge.(17)Precision micro pipettes.(18)Any such other equipments as may be necessary.(3)Any person having adequate space of not less than 500 sft. for each Clinic/Centre and being or employing;(i)Gynaecologist having experience of performing at least 20 procedures in chronic villa aspiration per vagina or per abdomen chronic villi biopsy amniocentesis, cordocentesis, foetoscopy, foetal skin or organ biopsy or foetal blood sampling etc. under supervision of an experienced gynaecologist in these fields.(ii)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 imaging scanning or(iii)A Medical Geneticist may set up a Genetic Clinic/ Ultrasound Clinic/Imaging Centre which shall have : (a)Equipments and accessories necessary for carrying out clinical examination by an obstetrician or gynaecologist.(b)An ultrasonography

machine including mobile ultrasound machine, imaging machine or any other equipment capable of conducting foetal ultrasonography.(c)Appropriate catheters and equipment" for carrying out chronic villi aspirations vagina or per abdomen.(d)Appropriate sterile needles for aminocentesis or cordocentesis.(e)A suitable foetoscopy with appropriate accessories for foetoscopy, foetal skin or organ biopsy or foetal blood sampling shall be options.(f)Equipment for dry and wet sterilization.(g)Equipment for carrying out emergency procedures such as evacuation of uterus or resuscitation in case of need.(h)Genetic Works Station.

### **3.**

-A. Sale of Ultrasound Machines, Imaging Machines (1) No organization including a commercial organization or a person imaging manufacturer, importer, dealer or supplier of ultrasound machine/imaging machine or any other equipments capable of detecting sex of foetus shall sell, distribute, supply or authorize the use of any such machine or equipment in any manner, whether on payment or otherwise to any Genetic Counselling Center, Genetic Laboratory, Clinic, body or person is registered under the Act.(2)The provider of such machine/equipment to any person registered under the Act shall sent to the J&K 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 or supplier of ultrasound machines/imaging machine or any other equipment capable of detecting sex of foetus, selling, distributing, supplying or authorizing in any manner the use of such machine or equipment to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any 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 shall not be used for detection of sex of foetus or selection of sex before or after conception.

### **4. Registration of Genetic Counselling Centre, Genetic Lab, and Genetic Clinic, Ultrasound Clinic and Imaging Centre**

(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 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 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 prominently display a notice that they do not conduct any technique/ test/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 office of the appropriate authority, nor/not than the next working day if received by post.

## 5. Application Fee

(1) Every application for registration under rule 4 shall be accompanied by an application fee of, (a) Rs. 3000/- for Genetic Counselling Centre, Genetic Lab, Genetic Clinic, Ultrasound Clinic or Imaging Centre ; (b) Rs. 6,000/- 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 Laboratory/Centre etc. has been rejected by the appropriate authority, no fee shall be required to be paid on resubmission 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 authority in the J&K Bank Ltd. payable at the Headquarters of the appropriate authority concerned. The fees collected by the appropriate authorities for registration of Genetic Counselling Centers, Genetic Lab, Ultrasound Clinic and Imaging Clinic 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 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, 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, Imaging Clinic to conduct one or more specified prenatal diagnostic tests or procedures depending upon the availability of place, equipment and qualified employees and standards maintained by such Laboratories or Clinics. (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) of rule 4 including inspection at the premises of the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound 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 of Form-C, as the case may be, within a period of ninety days from the date of receipt of application for registration.

## **7. Certificate of registration shall be non-transferable**

In the event of change of ownership, change of management as or on ceasing to function as Genetic Counselling, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre, both copies of the certificates of registration shall be surrendered to the appropriate authority. In the event of change of ownership or change of management of the Genetic Counselling, Genetic Laboratory, Genetic Clinic, Genetic Ultrasound, the new owner or manager of such Centre shall apply afresh for grant of certificate of registration.

## **8. Validity of registration**

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

## **9. Renewal of Registration**

(1) An application for renewal of certificate of registration shall be made in duplicate in Form-A, to the appropriate authority within 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 itself satisfying that the applicant has complied with 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 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 certificates of rejection shall be surrendered immediately to the appropriate authority by the Genetic Counselling Centre Genetic Clinic, Ultrasound Clinic or a Genetic 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 registration, the certificate of registration shall be deemed to have been renewed.

## **10. Maintenance and preservation of record**

(1) Genetic Counselling Centre, Genetic Clinic, Ultrasound Clinic, Imaging Centre shall maintain a register showing in serial order, the names and addresses of the men, or women given Genetic Counselling, subject to prenatal diagnostic procedures or prenatal diagnostic tests, the names of their spouses or father and the date on which they first reported for such counselling, procedure or test. (2) The record to be maintained by every Genetic Counselling Centre in respect of each women

counselled shall be as specified in Form-D.(3)The record to be maintained by every Genetic Laboratory in respect of each man or woman subjected to any prenatal diagnostic shall be specified in Form-E.(4)The record to be maintained by every Genetic Clinic in respect of each man or woman subjected to any prenatal diagnostic procedure shall be specified in Form-F.(5)The appropriate authority shall maintain a permanent record of applications for grant of renewal of certificates 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 record.(6)All case related records, forms of consent, laboratory results, microscope pictures, sonographic plates or slides, recommendations and letters shall be preserved by the Genetic Counselling, Centre, Genetic Laboratory, Genetic Clinic, Imaging Centre for a period of two years from the date of completion of counselling, prenatal diagnostic procedure or prenatal diagnostic tests as the case maybe. In the event of any legal proceedings, the records shall be preserved till final disposal of legal proceedings or till the expiry of the.said period of two years whichever is earlier.(7)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 I techniques, tests conducted by them in respect of each month, 5th day of the following month to the concerned appropriate authority.

## **11. Conditions for conducting prenatal procedure**

(1) Before conducting pre-implantation, genetic or any prenatal diagnostic technique/ test, procedure such as amniocentesis, chronic villi biopsy, foetoscopy, foetal skin or organ biopsy or cordocentesis, a written consent, as specified in Form-G in a language the person undergoing such procedure understands shall be obtained from her/him ;Provided that where a Genetic Clinic has taken sample of any body tissue or body fluid and sent 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 ultrasound/image scanning on a pregnant woman shall give a declaration on each report on ultrasound 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 sex of her foetus.(2)The State Government may issue translation of Form-G in languages used in the State 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.

## **12. Facilities for Inspection**

(1) Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Clinic, Nursing Home, Hospital, Institute or any other place where any of the machines or equipments capable to performing any procedure, technique or test capable of prenatal determination 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 in this behalf for registration of such institution by whatever name called under the Act or for detection of misuse of such facilities or advertisement therefore or for detection/ disclosure of cases of violation of provision of the Act in any other manner.(2)The appropriate authority or the

officer authorized by it may seal and seize ultrasound machine, scanner or any other equipment, capable of detecting sex of foetus used by any other organization may be released if such organization has not got itself registered under the Act. These machines of the organization may be released if such organization pays penalty equal to five times of 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.

### **13. Procedure for Search and Seizure**

(1) The appropriate authority or any other officer authorized in this behalf may enter and search at all reasonable times any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Imaging Clinic, Ultrasound Clinic in the presence of two or more independent witnesses for the purpose of search and examination of any record, register, document, book, pamphlet, advertisement or any other material object found therein and seal and seize the same if there is reason to believe that it may furnish evidence of commission of an offence punishable under the Act. Explanation. In these rules ;(i)Genetic Laboratory/Genetic Clinic/Genetic Counselling Centre shall 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, techniques or test for prenatal detection of sex of foetus is used ;(ii)Material object shall include records, machines and equipments; and(iii)Seize and seizure shall 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.(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, pamphlets, advertisement or any other material object have been seized Provided further 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 Clinic, if no person acknowledging custody of the document, record, register, book, pamphlet, advertisement or other material seized is available at the place of effecting the seizure.(4)If a material object seized is perishable in nature, the appropriate authority or the officer authorized in this behalf shall make arrangements promptly for sealing, identification and preservation of the material object and also convey it to a facility for analysis or test, if analysis or test be required: Provided that the refrigerator or other equipment used by the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic and Imaging Centre for preserving such perishable material object may be sealed until such time as arrangements can be made for safe removal of such perishable material object and in such eventuality, mention of keeping the material object 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 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, books or any other material object to be seized and prevent any tampering with such documents, records, books or any other material object.

#### **14. Intimation of changes in employees or equipment**

Every Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultra-sound Clinic and Imaging Centre shall intimate every change of employees, place, address and equipment, installed to the appropriate authority within a period of thirty days of such change.

#### **15. Conditions for analysis or test of prenatal diagnostic procedures**

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

#### **16. Meeting of the Advisory Committee**

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

#### **17. Allowances to the Members of The State Supervisory Board**

The Ex-officio members and other 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.

#### **18. 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 languages or language for the information of the public to the effect that disclosure of the sex of the foetus is prohibited under law. (2) At least one copy 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 or the State Government may publish periodically lists of registered Genetic Counselling Centres, Genetic Laboratory, Genetic Clinics and Imaging Centre and findings from the reports and other information in their possession for the information of the public and for use by the experts in the field.



## **19. Code of conduct to be observed by persons working at genetic counselling centres, genetic laboratories, genetic clinics, ultrasound clinics etc.**

All persons including the owner, employee or any other 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 qualification necessary for carrying out prenatal diagnostic techniques/procedures and tests including ultrasonography.(iii)Not conduct or cause to be conducted or aid in conducting by himself or through any other person any technique or test or procedures 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 procedures 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 purpose 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.