Chapter -III

Regulation of Assisted Reproductive Technology in India

3.1 Introduction

Assisted Reproductive Technology (ART) is now a fast growing global industry. Advances in scientific facilitation of conception offer infertile couples and individuals a lot of options, ranging from the low-tech process of artificial insemination (AI) to the more complex high-cost process of *in vitro fertilization* (IVF) and surrogacy. The growing industry of ART has led the development of markets in gametes, surrogates, and advanced clinical techniques. There are social, scientific, and commercial components associated with ART and as a result, there are a wide variety of players involved in the practice of ART, including clinics, hospitals, and related facilities; egg and sperm donors and surrogates; intended parents; and lawyers. In addition, third party reproductive techniques have created a market for agencies that, on the commercial basis, recruit egg and sperm donors and surrogates.

This development and use of medically ART is continuously raising a range of complex and profound social, legal and ethical issues: now the question is how should we react toward these developing markets? Do we seek to expand every individual’s capacity to achieve biological parenthood, or view reproductive potential as appropriately bounded? What role should the state play in providing individuals and families with access to reproductive technologies? What criteria should be used to determine who deserves to have medically assisted reproduction? What restrictions should be placed on ART? Definitely these are some questions which cannot be answered in isolation. The law always plays an important role to determine the role of state, public or private agencies and individual also. This chapter will try to find out the more specific answers to these questions through analyzing the regulatory mechanism.

3.2 Historical Background of Assisted Reproductive Technology in India

The world’s first IVF baby, Louise Brown, was born on July 25, 1978 in UK through the efforts of Dr. Robert G Edwards and Dr. Patrick Steptoe. Six years after the first test tube baby was born in the UK in 1978, the Indian government established an IVF project within its contraceptive research establishment, at the Institute for Research in Reproduction (now National Institute for Research in Reproduction or NIRR) in Mumbai. NIRR is an institution of the ICMR. In August 1984, the NIRR
set up an IVF programme in collaboration with the King Edward Memorial Hospital, a tertiary care center of the Bombay Municipal Corporation. IVF was tested on poor women seeking infertility services in this government hospital. The world’s second and India’s first IVF baby, Kanupriya, alias Durga, was born 67 days later on October 3, 1978 through the efforts of Dr. Subhas Mukherjee and his two colleagues in Kolkata. The techniques used by Mukherjee were markedly different from those used by Edwards and Steptoe. Mukherjee was the first person in the world to use (a) gonadotropins for ovarian stimulation prior to ovum pick-up in an IVF treatment cycle; (b) the transvaginal route by colpotomy for harvesting oocytes; and (c) freezing and thawing of human embryos before transferring them into the uterus that led to the successful birth of Durga. India’s first scientifically documented IVF baby, Harsha, was born on August 6, 1986 in Mumbai, through the collaborative efforts of the ICMR’s Institute for Research in Reproduction and the King Edward’s Memorial Hospital (KEM). This work was executed after being approved by the Scientific Advisory Committee of the ICMR’s Institute for Research in Reproduction and the Ethics Committee for Human Experimentation of the KEM Hospital. Births of IVF babies were reported subsequently during the same year by two other clinics in India.\footnote{National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, Indian Council of Medical Research National Academy of Medical Sciences (India), (2005, New Delhi) at 4.}

From August 6, 1986, when the first documented “test tube” baby in India was born,\footnote{Sandhya Srinivasan, Making Babies: Birth Markets and Assisted Reproductive Technologies in India, 2010, New Delhi, Zubaan), at xvi} since then, its slow expansion has been a gradual but steadily increasing phenomenon. ICMR supported National Institute of Reproductive Research (NIRR) to take up ART research and later to bring it in the Family Welfare Programme and tertiary care service institutions in the Ninth Five year Plan. The ICPD declaration at Cairo on reproductive rights and choices emphasized expanding the scope of reproductive health and thus promoted ART in the name of women’s choices and rights.\footnote{Imrana Qadeer, “New Reproductive Technologies and Health Care in Neo-Liberal India: Essays”, Centre for Women’s Development Studies, (November 2010) at 14.} Finally, India’s Ninth Five Year Plan introduced management of sterility in its comprehensive RCH Programme but not in the “Essential” package of RCH. It was said that given an estimate of 5-10 percent sterility, it is essential that couples who do not have children get access to essential clinical examination, investigation, management and counseling. It was proposed that while the expertise would be made available at the tertiary hospitals, basic services to detect causes and carry out
preliminary investigations like sperm count, diagnostic curettage, and tubal patency tests will be done at the CHC to screen cases and refer them to appropriate institutions. It is interesting that, while the Five year Plans committed to ARTs, the National Public Health Standards evolved for CHC under the NRHM did not include the simple test facilities. This commitment was repeated almost verbatim in the Tenth Five Year Plan yet, the broad framework for Implementation of the NRHM, while enumerating guaranteed services, talked only of treating RTI and ignored the simple tests for infertility at the CHC level. Thus, in the public sector these services are confined to the tertiary sector and therefore not accessible to the majority. We see then, that ART are a part of the glamour technologies projected by India to establish its international standards. It is however confined primarily to the private sector and tertiary public sector institutions accessible to a select few. The basic services have no strategy to deal with infertility.\(^4\)

The Indian Society for Assisted Reproduction has a membership of more than 600. Though the number of experts competent to perform advanced procedures is still small, there are approximately over 2,00,000 IVF clinics in India. In addition, smaller towns and rural areas have fertility centers that work with ART Centers located in the tertiary care institutions of cities where specialists are available to perform IVF and ICSI (Intra-Cytoplasm Sperm Injection) procedures.

### 3.3. Need for Regulation

The idea of the government restricting what scientists can or cannot research, or what treatment a doctor can offer a patient, are seen in some countries as improper government interference. Nevertheless the U.K’s regulation in this area is well established and is regarded by many countries in the world as a model system.\(^5\) There has been a much debate in the Indian medical community in last 10 years about whether there is any need for legislation in relation to the provisions of ARTs. There is a great deal of uncertainty as to how the law may respond to disputes which arise in relation to ART, such as those involving the ownership of gametes and embryos. ART is quite different from other medical treatments because the process involves the formation of a family and of course the interest of child born through this complex process.

\(^4\) Id at 15.
3.4 Scheme of Regulation

In order to ensure quality of care it is imperative that a proper accreditation procedure is followed in establishment of ART centers, which should follow standardized protocols and guidelines. National guidelines for accreditation, supervision and regulation of ART clinics have been formulated by ICMR in 2005 to provide optimum benefit of these newer technologies to appropriate persons by skilled team of experts, at affordable health and economic cost, in all public and private facilities in our country. A national registry pertaining to all centers that are accredited by the licensing authority shall be maintained at ICMR and shall contain records of treatment cycles and outcome. Equally important are issues related to the conduct of research with material obtained as byproducts from the clinical activity. These include the follicular fluid, oocytes, spare embryos, semen samples which can be used by researchers in basic or molecular science.\(^6\)

Prevention and appropriate treatment of infertility has been included in the ICPD (International Conference on Population and Development) Programme of Action; it follows that alleviation of infertility should be included as a component of the primary health care system. Most types of infertility such as reproductive tract infections (RTI) and genital tuberculosis are preventable and amenable to treatment. About 8% of infertile couples, however, need serious medical intervention involving the use of advanced ART procedures such as IVF or ICSI. Such advanced treatment is expensive and not easily affordable to the majority of Indians. Further, the successful practice of ART requires considerable technical expertise and expensive infrastructure.\(^7\)

To prevent misuse of pre-natal diagnostic techniques, the Pre-Natal Diagnostic Techniques Act-1994, was passed and amended as Pre Conception and Pre Nataal Diagnostic Techniques Act- 2002. The first reference to ARTs in an official document appeared in the “Ethical Guidelines for Biomedical Research on Human Participants” (herein after referred as ethical guideline) published by ICMR in 2000. Subsequently, in 2005, Indian Council of Medical Research (ICMR) and the National Academy of Medical Sciences (NAMS) framed the National Guidelines for Accreditation, Supervision and Regulation of the Assisted Reproduction Technology Clinics (herein after referred as ICMR guideline) to regulate the surrogacy. However,

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\(^6\) Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research. (2000, New Delhi), at 105.

\(^7\) Supra note 1, chapter 1.
since these guidelines had no legal binding and the rules and regulations therein were not mandatory, they were not strictly implemented, resulting in the absence of any form of regulation of ARTs. Recently, ICMR and Ministry of Health and Family Welfare (MOHFW) have come up with the Draft Assisted Reproductive Technology Bill & Rules 2008 (herein after referred as ART Bill) which was later modified in 2010.

3.4.1 Scheme of the Draft Assisted Reproductive Technology Bill & Rules 2010

The Draft Assisted Reproductive Technology Bill & Rules 2010 has divided into two sections- Bill and Rules. The nine chapters covered under the Bill include details on various aspects of the regulation of ART clinics, semen banks and research on embryos. In chapter I-III dealing with Registration and Regulatory Authorities, the Bill proposes that a National Advisory Board be set up to recommend modifications in the regulations regarding permissible ARTs, the minimum physical infrastructure of the ART clinics, guidelines for counseling, research on human embryos, and other policies on assisted reproduction. Moreover, all states are to establish State Boards, who may advice the state government to constitute a Registration Authority, monitor its functioning and hold enquiries. Chapter IV provides the duties of an assisted reproductive technology clinic, which include general duties, the duty to obtain written consent and maintain accurate records, duties for clinics using gametes and embryos, and duties regarding pre implantation genetic diagnosis and sex selection. Chapter V deals with sourcing, storage and handling of gametes and embryos, records to be maintained by semen banks, and restrictions on sale of gametes, zygotes and embryos. Chapter VI provides regulation of research on embryos, gametes, or other human reproductive material sourcing. Chapter VII discusses on rights and duties of patients, donors, surrogates and determination of the status of the child, the right of the child to information about donors and surrogate mothers. Chapter VIII provides offences and penalties and chapter IX covers certain miscellaneous provisions. The Bill is followed by the Rules, which seek to provide an explanatory background on the various sections of the Bill.

3.5 Regulatory Mechanism for ARTs

The National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India 2005 have made elaborated provisions regarding ART clinics.
3.5.1 Minimal Physical Requirements for an ART Clinic

The present guidelines require a well designed ART clinic of Level 2\(^8\) or Level 3\(^9\) having a non-sterile\(^{10}\) and a strictly sterile area. Some of the spaces could be combine (that is, the same space may be used for more than one purpose) as long as such a step does not compromise the quality of service. However, the space prescribed for the sterile area cannot be combined with those for the non-sterile area and vice-versa. For level 1B infertility care units a strictly sterile area will not be required. The space requirement\(^{11}\), however, will include, a reception area, a waiting room for the patients, a consulting room for the gynecologist, and requirements mentioned under and the non-sterile area, a reception and waiting room for patients, a room with privacy\(^{12}\). Evaluation of infertility necessitates history taking of the most intimate sexual practices between the couples followed by close examination of the reproductive tract and sexual organs.

It also emphasizes on maintaining the strict privacy and dignity of the patients. In case a male doctor examines a female patient, there must always be a female attendant present. The room must be equipped with an examination table and gynecological instruments for examining the female per vaginum, an appropriate ultrasonographic machine with a probe for transvaginal examination of the female and examination of the testes and excurrent male reproductive tract. A colour Doppler would be useful but not essential. A general-purpose clinical laboratory, store room\(^{13}\), record room\(^{14}\), autoclave room\(^{15}\), semen collection room\(^{16}\), semen processing

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8 Id. para 2.5.3
9 Id para 2.5.4
10 The non-sterile area must include what is listed under id at sections 1.3.1.1 to 1.3.1.9 Sections 2.5.3 and 2.5.4)
11 Id para 1.3.1.8, 1.3.1.9
12 A room with privacy for interviewing and examining male and female partners independently is essential.
13 A well-stocked store for keeping essential stock of especially those items that have to be imported, precluding the need to be caught short in the middle of treatment. Facilities must be available for storing sterile (media, needles, catheters, Petri dishes and such-like items) and non-sterile material under refrigerated and non-refrigerated conditions as appropriate.
14 Record keeping must be computerized as far as possible so that data is accessible retrospectively for analysis or when called upon by the supervisory agency. There are many software programmes for this purpose, which are commercially available today. Besides containing essential details of the patient’s records, it must contain history of the cause of infertility as diagnosed earlier, results of new diagnosis if relevant, the treatment option best suited for the particular patient, the treatment carried out and the outcome of treatment, and follow-up if any. Any other noteworthy point such as possible adverse reaction to drugs must be recorded. ICMR should make an effort to devise a form for basic data recording, which would be suitable for India.
15 A separate facility must be available for sterilizing and autoclaving all surgical items as well as some of those to be used in the in vitro culture laboratory
laboratory\textsuperscript{17} clean room for IUI\textsuperscript{18}, the sterile area\textsuperscript{19}, the operation theatre\textsuperscript{20} room for intrauterine transfer of embryo\textsuperscript{21} and the embryology laboratory complex.

The embryology laboratory must have facilities for the control of temperature and humidity and must have filtered air with an appropriate number of air exchanges per hour. Walls and floors must be composed of materials that can be easily washed and disinfected; use of carpeting must be strictly avoided.\textsuperscript{22} All material from the operation room, culture dishes and Falcon tubes for sperm collection (including lids), must bear the name of the patient. In the incubator, identified oocytes and sperm are to be kept together on the same tray and double-checked. Pipettes used should be disposed off immediately after use. The embryology laboratory must have a daily logbook in which all the day’s activities are recorded, including the performance of the equipment.

It require infertility clinic to a ready access to laboratories that are able to carry out immunoassays of hormones (FSH, LH, Prolactin, HCG, TSH, Insulin, Estradiol, Progesterone, Testosterone and DHEA) and tests such as for HIV and Hepatitis B. Endocrine evaluation constitutes an essential diagnostic procedure to determine the cause of infertility. It also necessitate to estimate blood estradiol in

\textsuperscript{16} This must be a well-appointed room with privacy and an appropriate environment; it should be located in a secluded area close to the laboratory. Such a facility must be available in-house rather than having the patient collect the sample and bring it to the laboratory for analysis as, in the latter case, semen quality and identity is likely to be compromised. Procedures for collection of semen as described in the WHO Semen Analysis Manual must be followed with special reference to the type of container used; these containers must be sterile, maintained at body temperature and nontoxic. This room must have a washbasin with availability of soap and clean towels. The room must also have a toilet and must not be used for any other purpose.

\textsuperscript{17} There must be a separate room with a laminar air flow for semen processing, preferably close to the semen collection room. This laboratory must also have facilities for microscopic examination of post-coital test smears. Good Laboratory Practice (GLP) guidelines as defined internationally must be followed.

\textsuperscript{18} There must be a separate area/room with an appropriate table for Intra-Uterine Insemination (IUI).

\textsuperscript{19} The sterile area shall house the operation theatre, a room for intrauterine transfer of sperm or embryos and an adjoining embryology laboratory. Entry to the sterile area must be strictly controlled by an anteroom for changing footwear, area for changing into sterile garments and a scrub-station. The sterile area must be air-conditioned where fresh air filtered through an approved and appropriate filter system is circulated at an ambient temperature (22-25\textdegree{}C).

\textsuperscript{20} This must be well equipped with facilities for carrying out surgical endoscopy and transvaginal ovum pick-up. The operation theatre must be equipped for emergency resuscitative procedures.

\textsuperscript{21} This room must be a sterile area having an examination table on which the patient can be placed for carrying out the procedure and rest undisturbed for a period of time.

\textsuperscript{22} The embryology laboratory must have the following: a laminar flow bench with a thermostatically controlled heating plate, a stereo microscope, a routine high-powered binocular light microscope, a ‘high resolution’ inverted microscope with phase contrast or Hoffman optics, preferably with facilities for video recording, a micromanipulator (if ICSI is done), a CO\textsubscript{2} incubator, preferably with a back up, a hot air oven, a laboratory centrifuge, equipment for freezing embryos in a programmed manner, liquid nitrogen cans, a refrigerator. Appropriate steps need to be taken for the correct identification of gametes and embryos to avoid mix-ups.
samples taken from a woman undergoing controlled ovarian hyper stimulation, and have the result on the same day to determine the dose of drugs to be given for induction of ovulation. Accurate monitoring of endocrine response to controlled ovarian stimulation goes a long way in preventing ovarian hyper stimulation.23

It also emphasizes another important facility in an ART clinic (or easily accessible to it) that of a microbiology laboratory that can carry out rapid tests for any infection, and a clinical chemistry laboratory. Facilities for carrying out histopathological studies on specimens obtained from the operation theatre would also be desirable.24

Each laboratory has to maintain in writing, standard-operating manuals for the different procedures carried out in the laboratory. The patient’s name should be clearly labeled on all the tubes, dishes and pipettes containing the gametes and embryos. All pipettes should be immediately discarded after use.25 Periodical check for microbial contamination using standard techniques, and a record of it is required for laminar flowhoods, laboratory tables, incubators and other areas where sterility is required. A logbook is required to records the temperature, carbon dioxide content and humidity of the incubators and the manometer readings of the laminar air flow. All instruments must be calibrated periodically (at least once every year) and a record of such calibration maintained.

3.5.2 Essential Qualifications of the ART Team

The practice of ART requires a well-orchestrated teamwork between the gynaecologist26, andrologist27 and the clinical embryologist28 supported by a

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23 Id para 1.3.3.1.
24Id para 1.3.3.2
25 Id para 1.3.3.3
26 The minimal qualification for a gynaecologist in a Level 1B, Level 2 or Level 3 clinic (see Paras 2.5.2, 2.5.3 and 2.5.4) is a post-graduate diploma or degree in gynaecology. Additional experience should include the Understanding the causative factors of male and female infertility, Acquiring knowledge of the practice and use of diagnostic methods for determining the cause of infertility, Acquiring knowledge of the clinical aspects of reproductive endocrinology and the reproductive defects caused by endocrine factors, and an understanding of the limitations of the currently used hormone assay methods, and of the techniques available for medically or surgically correcting endocrine disorders, Acquiring competence/skills in gynecological ultrasonography to diagnose reproductive tract anomalies, monitoring ovarian and uterine response to ovarian stimulation, picking up oocytes at the most appropriate time, and transferring embryos by any one of the several methods currently available to handle embryo transfer in ‘difficult cases’, The gynaecologist must be well versed, particularly in the pharmacology of hormone action, and know how to avoid situations such as Ovarian Hyperstimulation Syndrome that can pose a great health hazard.
27 Fifty percent of infertility cases are related to male factors, many of which can be treated by specific ART procedures or other less invasive procedures. Andrology, a subject related to male reproduction, does not constitute a formal course in the medical curriculum in India, although several journals in
counsellor\textsuperscript{29} and a programme coordinator/director\textsuperscript{30}. The staff requirements would be mandatory for Level 2\textsuperscript{31} and Level 3\textsuperscript{32} clinics. In the case of small Level 2 and Level 3 clinics, the services of the andrologist, the clinical embryologist and/or the counsellor could be shared.

The responsibilities of the gynaecologist would include the interviewing of the infertile couple initially, history taking, physical examination of the female, recommending appropriate tests to be carried out, interpreting them and treating medical disorders (infections, endocrine anomalies), carrying out laparoscopy or sonohysterosalpingography for determining the status of the uterus and the fallopian tube, advising the couple on planned relationship in simple cases, carrying out AIH, AID, IUI, IVF or ICSI as the case may warrant, based on diagnostic evidence. In case of male factor infertility, if the gynaecologist is confident and competent, he/she can treat such cases or refer them to the andrologist. The treating doctor is responsible for maintaining all records of diagnosis, treatment given and consent forms, and also to

\textsuperscript{28} The clinical embryologist must be knowledgeable in mammalian embryology, reproductive endocrinology, genetics, molecular biology, biochemistry, microbiology and in vitro culture techniques. The biologist must also be familiar with ART. He/she must be either a medical graduate or have a post-graduate degree or a doctorate in an appropriate area of life sciences.

\textsuperscript{29} Counsellors are an important adjunct to any infertility clinic. Indeed, in the UK, counsellors are appointed by the clinic but they report to an independent body. This ensures that there is fair play by the clinic and the patients are adequately informed of what and what not to expect from the treatment offered to them. Counselling for ART is not taught as a separate subject anywhere. A person who has at least a degree (preferably a postgraduate degree) in Social Sciences, Psychology, Life Sciences or Medicine, and a good knowledge of the various causes of infertility and its social and gender implications, and the possibilities offered by the various treatment modalities, should be considered as qualified to occupy this position. The person should have a working knowledge of the psychological stress that would be experienced by potential patients, and should be able to counsel them to assuage their fears and anxiety and not to have unreasonable expectations from ART. A member of the staff of an ART clinic who is not engaged in any other full-time activity in the clinic can act as a counsellor.

\textsuperscript{30} This should be a senior person who has had considerable experience in all aspects of ART. The programme co-ordinator/director should be able to co-ordinate the activities of the rest of the team and take care of staff administrative matters, stock keeping, finance, maintenance of patient records, statutory requirements, and public relations. He/she should ensure that the staff are keeping up with the latest developments in their subject, by providing them with information from the literature, making available to them access to the latest journals, and encouraging them to participate in conferences and meetings and present their data. The programme co-ordinator/director should have a post-graduate degree in an appropriate medical or biological science. In addition, he/she must have a reasonable experience of ART.
refer the couple for counselling. It would be the gynaecologist’s responsibility to see that all equipment and instruments in the operation theatre are properly functional and in order, and that a logbook is maintained of their use and operation.

The andrologist must have knowledge of the occupational hazards, infections and fever that cause reversible or irreversible forms of infertility, and knowledge of ultrasonographic or vasographic studies of the reproductive excurrent ducts to detect partial occlusion that can be surgically corrected. An individual may act as an andrologist for more than one clinic but each clinic owns the responsibility for the andrologist and ensure that the andrologist is able to take care of the entire work load of the clinic without compromising on the quality of service.

The responsibilities of the andrologist would includes Recording case histories, Prescribing appropriate diagnosis and treatment based on the diagnosis, Carrying out such surgical procedures as warranted by the diagnosis, Maintaining all the records, from the case history to the treatment given, and the patient consent forms, Referring the couple to the gynaecologist for carrying out the appropriate ART procedure if necessary, after the male factor has been duly investigated, Referring the couple to the counsellor if necessary, In cases of surgical intervention, making sure that the operation theatre is fully functional and all supplies are available before the start of any surgical procedure, Entering any deficiency that needs attention in the operation theatre logbook.

Clinical Embryologist must be familiar with the Principles and practice of semen analysis and cryopreservation of semen, Cytology of mammalian and human oocyte to identify stages of oocyte maturation accurately, All aspects of embryology including developmental biology, Cell biological techniques, Molecular biology and genetics of human reproduction, Micromanipulation of sperm and oocytes for carrying out ICSI and single-cell biopsies of embryos for pre-implantation genetic diagnosis, Principles and functioning of all the equipment used in the laboratory, In vitro fertilization of oocytes after processing the gametes, Principles and practice of embryo freezing. The responsibilities of the clinical embryologist would be to ensure

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33 In case of shortage of adequately trained clinical embryologists, an individual may act as a clinical embryologist for more than one clinic but each clinic where the person works must own responsibility for the embryologist and ensure that the embryologist is able to take care of the entire work load of the clinic without compromising on the quality of service. An embryologist must not be associated with more than two centers at any given time.
that all the necessary equipments are present in the laboratory and are functional, To perform all the procedures pertaining to processing, handling and culturing of gametes and embryos in the laboratory and hand over the embryo to the gynaecologist, To maintain records of all the procedures carried out in the laboratory.

The counsellor must invariably appraise the couple of the advantages of adoption as against resorting to ART involving a donor. An individual may act as a counsellor for more than one clinic but each clinic must own responsibility for the counsellor and ensure that the counsellor is able to bear the entire counselling load of the clinic without compromising on the quality of the counselling service.

It would be the responsibility of the National Accreditation Committee to ensure that the list given in the guidelines be enlarged in real time as progress occurs in the field. It is hoped that the practitioners of ART in the country will bring to the notice of the Committee on a continuing basis, any new procedure for the practice of which there would appear to be a sound scientific case. The National Accreditation Committee or a body appointed by it will approve or disapprove the new procedure within six months of its having been made aware of in writing; if this is not done, the clinic could continue to use the procedure until the above body has taken a decision on it. No new procedure that has not been approved as above should be permitted to be used by an infertility clinic for more than the period mentioned above. One of the primary concerns of all ART treatments is the safety of the patients and of their gametes and embryos which constitute the very beginning of a new individual’s life. The basic tenets of any medical treatment mentioned in the Helsinki Declaration of 1964 and reiterated in October 2000 in Scotland clearly spell out the ethical concerns of treating patients. These basic tenets are also applicable to ART. The clinic must ensure that a particular ART being offered is fully in consonance with the diagnosis made of the cause of infertility. More particularly, the clinic must make sure that patients are well informed about the treatment being offered to them, the reasons of suggesting a particular form of treatment, and alternative therapies available if any.

If a clinic is offering an ART that is not listed in these guidelines now or as modified in the future, the procedure must be approved by the clinics ethics committee (constituted as recommended by the ICMR ethical guidelines, 2000), justifying the need for the procedure and explaining why alternatives are not suitable.

34 Id para 1.6.
35 Ibid.
[Only clinics of (Level 2 or Level 3)\textsuperscript{36} would be required to have an ethics committee.] Informed consent from the patients would be mandatory in such cases as well. As mentioned in Para one of this section, the clinic must also bring the new procedure to the notice of the National Accreditation Committee for its approval; if such an approval is not granted, all further use of the procedure must stop.\textsuperscript{37} Clinics which should be Registered Clinics involved in any one of the following activities should be regulated, registered and supervised by the State Accreditation Authority/State Appropriate:

- Any treatment involving the use of gametes which have been donated or collected or processed in vitro, except for AIH, and for IUI by level 1A clinics who will not process the gametes themselves.
- Any infertility treatment that involves the use and creation of embryos outside the body.
- The processing or /and storage of gametes or embryos.
- Research on human embryos.

The term ART clinic used in guidelines refers to a clinic involved in any one of the first three of the above activities.

The Guidelines also make code of practice for ART clinics. Those areas which most affect the doctors, scientists and patients and are a part of this code are summarized below.

- Staff: A ‘person responsible’ shall take full responsibility for ensuring that the staff of the registered unit is sufficiently qualified, that proper equipment is used, that genetic material is kept and disposed -off properly, and that the center complies with the conditions of its registration.\textsuperscript{38}
- Facilities: Proper systems for monitoring and assessing practices and procedures are required to be in place in order to optimize the outcome of ART.
- Confidentiality: Except with the consent of the person(s) to whom the information relates, or in a medical emergency concerning the patient, or a

\textsuperscript{36} Id para 2.5.3 and 2.5.4.
\textsuperscript{37} Id para 1.6.
\textsuperscript{38} Guidelines for minimum standards and qualifications of clinical, scientific and counselling staffs are laid down in Chapter 1. Failure of the ‘person responsible’ to comply with the mandatory code of practice can lead to his/her removal or prosecution, or to the suspension of the clinic’s registration.
court order any information related to couples or donor under treatment will not be disclosed to anyone other than accreditation authority

- Information to patient: The patient has to be fully informed regarding limitations results and possible side-effects of the proposed treatment, the techniques involved, the availability of counselling and other treatments the cost of the treatment, the rights of the child born through ART, and the need for the clinic to keep a register of the outcome of a treatment.

- Consent: written consent of the couple on the standard form is required at all the possible stages of that treatment, including the possible freezing of supernumerary embryos. Specific consent must be obtained from couples who have their gametes or embryos frozen, in regard to what should be done with them if he/she dies, or becomes incapable of varying or revoking his or her consent.

- Counselling: it is mandatory that people seeking registered treatment must be given a suitable opportunity to receive proper counseling (support or therapeutic) about the various implications of the treatment.\(^{39}\).

- Use of gametes and embryos: maximum three oocytes or embryos may be placed in a woman in any one cycle, regardless of the procedure/s used, except under exceptional circumstances (such as elderly women, poor implantation, adenomiosis, or poor embryo quality) which should be recorded. A woman should not be treated with gametes or with embryos derived from the gametes of more than one man or woman during any one-treatment cycle.

- Storage and handling of gametes and embryos: The ‘highest possible standard’ in the storage and handling of gametes and embryos in respect of their security, and in regard to their recording and identification, should be followed.

- Research: The accreditation authority must approve all research that involves embryos created in vitro. A separate registration for each research project involving human embryos is required. The accreditation authority will give a registration certificate after being satisfied that the use of human embryos is essential for the purposes of the proposed research and the research is in public interest. It also states that no human embryo may be placed in a non-

\(^{39}\) (of Levels 1B, 2 or 3)
human animal and all research projects must be approved by the Institutional Ethics Committee before submission to the accreditation authority.\textsuperscript{40}

- **Complaints:** All registered ART clinics are required to have procedures for acknowledging and investigating complaints, and to have a nominated person to deal properly with such complaints. The accreditation authority must be informed of the number of complaints made in any year and those that are outstanding.

### 3.5.3 Responsibilities of the Clinic

The responsibilities of the ART clinic described under the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India are as follows:

- The clinic has to inform the patients about various options of treatment available (including the cheapest possible course of treatment), and help them in exercising the choices.
- To maintain records in an appropriate proforma (to be prescribed by the authority) to enable collation by a national body.
- When commercial DNA fingerprinting becomes available, to keep on its record, if the ART clinic desires and couple agrees, DNA fingerprints of the donor, the child, the couple and the surrogate mother should be done.
- To keep all information about donors, recipients and couples confidential and secure. The information about the donor (including a copy of the donor’s DNA fingerprint if available, but excluding information on the name and address – that is, the individual’s personal identity) should be released by the ART clinic after appropriate identification, only to the offspring and only if asked by him/her after he/she reaches the age of 18 years, or as and when specified and required for legal purposes, and never to the parents (except when directed by a court of law).
- To maintain appropriate, detailed record of all donor oocytes, sperm or embryos used, the manner of their use. These records are to be kept for at least ten years after which the records would transfer to a central depository to be maintained by

\textsuperscript{40} National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, Indian Council of Medical Research National Academy of Medical Sciences (India), New Delhi, 2005, Section 3.17 says: Each ART clinic of Levels 1B, 2 and Level 3 must have its own ethics committee constituted according to ICMR Guidelines, comprising reputed ART practitioners, scientists who are knowledgeable in developmental biology or in clinical embryology, a social scientist, a member of the judiciary and a person who is well-versed in comparative theology. Should the local ART clinic have difficulty in establishing such a body, the state accreditation authority should constitute such a body, co-opting a representative of the ART clinic.
the ICMR. If the ART clinic/centre is wound up during this period, the records must be transferred to the central repository in the ICMR.

- The schedule of all its charges has to be suitably displayed in the clinic and made known to the patient at the beginning of the treatment without any extra charges.
- To ensure that no technique is used on a patient for which demonstrated expertise does not exist with the staff of the clinic.
- The ART clinic will be totally transparent in all its operations. Thus it must inform the patient about the success rates of the clinic with regard to the procedure intended to be used on the patient.
- To have all consent forms available in English and local language(s).

Chapter IV of the Draft Assisted Reproductive Technology Bill and Rules 2010 make provisions regarding duties of assisted reproductive technology clinics.

3.5.4 General Duties of Assisted Reproductive Technology Clinics

Apart from above the bill also entrusts the ART clinics with certain responsibilities which are as under:

Firstly, ART clinics has to ensure the eligibility of patients, donors of gametes and surrogate mothers to avail assisted reproductive technology procedures under the criteria prescribed by the rules under this Act and to test them medically for any diseases, sexually transmitted or otherwise, as may be prescribed and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child.

Then ART clinic shall also obtain, from ART bank(s), all relevant information, except the name, personal identity and address, of possible gamete donors and assist the couple or individual desirous of the donation, to choose the donor. When an ART bank receives a request from an ART clinic for a donor oocyte, a responsible member of the staff of the ART bank will accompany the particular donor to the ART clinic, and obtain a written agreement from the authority designated for this purpose by the clinic, that the clinic shall, under no circumstances (except when asked by a court of law), reveal the identity of the donor to the recipient couple or individual or to anyone else; the clinic shall also ensure that all its staff is made

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41 Supra note 1 para 3.3.
aware of the fact that any step leading to disclosure of the identity shall amount to an offence punishable under this Act.

ART clinics shall obtain donor gametes from ART banks that have ensured that the donor has been medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child. ART clinics shall provide professional counseling to patients or individuals about all the implications and chances of success of ART procedures in the clinic and in India and internationally, and shall also inform patients and individuals of the advantages, disadvantages and cost of the procedures, their medical side effects, risks including the risk of multiple pregnancy, the possibility of adoption, and any such other matter as may help the couple or individual arrive at a decision that would be most likely to be the best for the couple or individual.

ART clinic is also responsible to inform couples or individuals, as the case may be about the rights of a child born through the use of ART. ART clinic will also explain the couple reasons, advantage, disadvantage and limitation of the recommended treatment. The clinic is also responsible to keep the information about clients, donors and surrogate mothers confidential and the information about treatment shall only be disclosed to central database, to be maintained by the Department of Health Research. The information may be disclosed at the request of the person or persons, in a medical emergency or by an order of a court of competent jurisdiction with the consent of the person or persons or the closest available relative of such person or persons to whom the information relates.

The ART clinic shall not consider conception by surrogacy for patients to whom it would normally be possible to carry a baby except if unsafe or undesirable medical implications of such conception arise the use of surrogacy may be permitted. ART clinics shall provide to couples or individuals, as the case may be, a pre-stamped self-addressed envelope to inform the clinic of the results of the ART procedure performed for the couple or the individual. ART clinic is prohibited to obtain or use sperm or oocytes donated by a relative or known friend of either of the parties seeking ART treatment or procedures. Every ART clinic shall establish a mechanism to look into complaints in such manner as may be prescribed. Minimum age of women is held to be 21 years below which, any assisted reproductive procedure performed, shall amount to an offence punishable under the bill. All ART clinics shall issue to the
infertile couple/individual discharge certificate stating details of the ART procedure(s) performed on the couple / individual. Only a registered ART bank (and no other organization) shall be authorized to advertise for, procure or provide semen, oocyte donor or surrogate mother.

3.5.5 Duty of the Assisted Reproductive Technology Clinic to Obtain Written Consent

Assisted reproductive technology clinic has to obtain consent in writing to perform any treatment or procedure of ART of all the parties seeking ART to all possible stages of such treatment or procedures including the freezing of embryos. An ART clinic shall freeze any human embryos with specific instructions and consent in writing from all the parties seeking ART in respect of what should be done with the gametes or embryos in case of death or incapacity of any of the parties. No ART clinic shall use any human reproductive material to create an embryo or use an in vitro embryo for any purpose without the specific consent in writing of all the parties to whom the ART relates. The consent of any of the parties obtained under this section may be withdrawn at any time before the embryos or the gametes are transferred to the concerned woman’s uterus.

3.5.6 Duty of the Assisted Reproductive Technology Clinic to Keep Accurate Records

- All ART clinics shall maintain detailed records, in such manner as may be prescribed, of all donor oocytes, sperm or embryos used, the manner and technique of their use, and the individual or couple or surrogate mother, in respect of whom it was used.

- All ART clinics will, as and when such central facilities are established, put on line all information available to them in regard to progress of the patient (such as biochemical and clinical pregnancy) within seven days of the information being available, withholding the identity of the patient.

- Records shall be maintained for at least a period of ten years, upon the expiry of which the ART clinic shall transfer the records to a central database of a national ART registry to be set up by the Department of Health Research at the Head quarters of the ICMR.

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43 Id section 21
44 Id section 22
45 section 22(i)
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- In the event of the closure of any ART before the expiry of the period of ten years, the ART clinic or ART bank shall immediately transfer the records to a central database of a national ART registry to be set up by the Department of Health Research at the Hqrs of the ICMR

3.5.7 Duties of Assisted Reproductive Technology Clinics Using Gametes and Embryos

Under this section Assisted reproductive technology clinics shall harvest oocytes in accordance with such regulations of the National Board or concerned State Board or any rule as may be prescribed under the bill. Then number of oocytes or embryos that may be placed in a woman in any one cycle shall be according to the rules and regulations also. The woman cannot be treated with gametes or embryos derived from the gametes of more than one man or woman during any one treatment cycle. An ART clinic cannot mix semen from two individuals before use. In case of multiple pregnancies as a result of ART, the concerned ART clinic shall inform the patient immediately of the multiple pregnancy and its medical implications and may carry out foetal reduction after appropriate counselling. The gametes from a person whose death is imminent shall only be collected if such person’s spouse intends to avail assisted reproductive technology to have a child. ART clinic shall not use ova that are derived from a foetus, in any process of in vitro fertilisation. The ART clinic shall utilise medically analysed semen whether from an ART bank or otherwise, for any aspect of ART. Any contravention of stipulation under sub-section 3, 4, 7 and 8 of this section shall amount to an offence under this Act.

3.5.8 Pre-implantation Genetic Diagnosis

Pre-implantation Genetic Diagnosis is allowed only to screen the embryo for known, pre-existing, heritable or genetic diseases or as specified by the Registration Authority. The State Board may lay down other conditions in the interests of Pre-implantation Genetic Diagnosis as it deems fit.

3.5.9 Sex Selection

Under this section the bill not only prohibit ART clinic to provide a couple with a child of a pre-determined sex but makes it a criminal offence for anyone to do any act, at any stage, to determine the sex of the child to be born through the process

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46 Id section 23
47 Id section 24
48 Id section 25
of assisted reproductive technology. So no one shall knowingly provide, prescribe or administer anything that would ensure or increase the probability that an embryo shall be of a particular sex, or that would identify the sex of an in vitro embryo, except to diagnose, prevent or treat a sex-linked disorder or disease. Also assisted reproductive technology clinic is restricted to carry out any procedure to separate, or yield fractions enriched in sperm of X or Y variations. Any contravention of provisions this section is held to be an offence.

**3.5.10 Responsibilities of the Accreditation Authority**

The State Governments through its Department of Health and/or Family Welfare will set up a State Accreditation Authority to oversee all policy matters relating to Accreditation, Supervision and Regulation of ART Clinics in the states in accordance with the National Guidelines. The State Government may also set up appropriate authorities for implementation of the Guidelines for the whole or a part of State having regard to the number of the ART Clinics.

Appropriate authority would have right to visit individually or collectively, any ART Clinic/Centre(s) accredited or not accredited, once a year with or without prior information to the clinic/center, to determine if the ethical guidelines and operative procedures mentioned here are being followed. The appropriate authority will point out the lapses to the clinic/center in writing. If these lapses continued for a maximum period of six months, the appropriate authority would recommend the State Accreditation Authority that the clinic/center may be ordered to be closed.

The appropriate authority may have delegated powers to impose a fine or a penalty on the center/clinic. An appropriate authority would consist of appropriately qualified scientists, technologists and sociologists and this authority will also be authorized to visit and regulate semen banks. In addition to the above, the Ministry of Health and Family Welfare, Govt. of India, will set up a National Advisory Committee to advise the Central Government on policy matters relating to regulation of ART Clinics. The State Accreditation Authority will have the rights and the responsibility of fixing the upper limit of charges for gamete donation and surrogacy and of revising these charges from time to time.

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49 Supra note 1, para 3.15.
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3.5.11 Establishing a National Database for Human Infertility\(^{50}\)

It is important to realize that diagnostic and therapeutic approaches in reproductive medicine have to keep pace with rapidly developing molecular knowledge of human reproduction. Now it is possible to detect the incidence of chromosomal abnormalities using a variety of high-powered PCR techniques (Human Reproduction 13: 3032-3038, 1998.) and multi colour fluorescent in situ hybridization (FISH) analysis. FISH studies on sperm are becoming necessary to understand whether there is a genetic cause for male infertility, before patients can be subjected to ICSI. New spermatogenesis genes are bound to be discovered testing their mutation will become easier with DNA chips and microarray technology. Unfortunately, there is no documented database available in our country that would cover data on all aspects of infertility, and there is an urgent need for the same. It is worrisome to see that, with the primary aim of providing a child to the infertile couple, a variety of sophisticated ART are being used to overcome male factor infertility without understanding the underlying cellular and molecular etiology. In the process of curing infertility in the patient, there is a high iatrogenic risk of transmitting an abnormal paternal geno-(pheno-)type to the ART-born child. An appropriate database would allow the quantification of such risks.

3.5.12 Composition of the National Advisory Committee:

It will comprise of a Chairman\(^{51}\) Secretary, Ministry of Health and Family Welfare, Govt. of India, Co-chairman; Director General, Indian Council of Medical Research, New Delhi, Executive Secretary; An officer below the rank of Joint Secretary in Ministry of Health and Family Welfare, Govt. of India, and the following Members:

- Representative of the Indian Council of Medical Research .
- Representative of the National Academy of Medical Sciences.
- Representative from the Ministry of Health & Family Welfare, Govt. of India.
- Representative of a scientific society that deals with ART\(^{52}\).
- A social scientist of repute.
- The Chairman of the National Bioethics Committee.

\(^{50}\) Supra note 1, Chapter 8,

\(^{51}\) Ibid.

\(^{52}\) Care must be taken to ensure that such a representative should be from a society that has democratically elected office bearers and is governed by reasonable rules and regulations. The representative must have a proven track record of having contributed significantly to ART. The nature of the person’s association with commercial companies must be made known publicly.
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- A gynaecological endocrinologist.
- A gynaecological sonographist.
- An operative gynaecologist.
- A mammalian reproductive biologist.
- An andrologist.
- A representative of NGOs.
- A counsellor.
- A representative of patients.
- A medico-legal expert.
- A representative of FOGSI.
- A representative of ISSRF.

3.5.13 Constitution of Authorities to Regulate Assisted Reproductive Technology

In the scheme of The Draft Assisted Reproductive Technology Bill and Rules 2010, there are authorities for regulation of ARTs at national level and state level.

3.5.14 National Advisory Board

The Bill proposes to establish a National Advisory Board for ART, having jurisdiction and powers and discharging the functions and duties conferred on it. Central Government may prescribe the number of members of the National Board, not exceeding twenty one. Also unless the rules otherwise provide, under the Bill, National Board shall consist of the following –

- Secretary, Department of Health Research, Government of India, shall be the Chairman of the Board;
- A senior scientist having knowledge of assisted reproductive technology, from the Department of Health Research or the Indian Council of Medical Research, shall be the Member-Secretary of the Board;
- A representative, not below the rank of Joint Secretary, from the Ministry of Health and Family Welfare;
- The nominee of an Indian professional society concerned primarily with assisted reproduction;
- Up to sixteen other experts of whom one each shall be a nominee of the Ministry of Health and Family Welfare and Indian Council of Medical Research, and at least six of whom shall be women in the fields of assisted

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53 Supra note 42, Chapter II, Section 3,
reproduction, gynecology, embryology, andrology, bioethics, mammalian reproduction, medical genetics, social science, law, or human rights, to be nominated by the Central Government.

- The Chairman of National Board shall nominate a Vice Chairman from among its members.

3.5.15 Meetings of National Advisory Board

The meetings of National Board may be held when necessary but at least twice a year and at such time and place in the country as the Chairperson of the National Board may think fit. The Chairperson shall preside over these meetings and in his absence the Vice-Chairperson of the National Board shall preside over the meetings of it.

3.5.16 Functions of National Advisory Board

The Bill authorizes the National Board to recommend modification from time to time in the attached rules and schedules where relevant, and performs any other functions and tasks assigned to it by the Central Government. It may recommend minimum requirements related to staff and physical infrastructure for various categories of assisted reproductive technology clinics may regulate the permissible assisted reproductive technology procedures and the selection of patients for assisted reproductive technology procedures and to encourage and promote the training and research in the field of assisted reproduction, and also to encourage the establishment and maintenance of a national database in respect of infertility. It may provide guidelines for counselling and necessary information and advice to patients on various aspects of assisted reproductive technology procedures, also ways and means of disseminating information related to infertility and assisted reproductive technologies to various sections of the society and to regulate the research on human embryos. It may provide Proformae for obtaining information, consent forms for various procedures, and contracts and or agreements among the parties involved, in all of the languages listed in the Eighth Schedule of the Constitution. It also may frame policies from time to time on assisted reproduction.

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54 Id section 4
55 Id section 5
3.5.17 Establishment of State Boards\textsuperscript{56} –

The Bill provides that every State Government shall, within 180 days of the issue of notification in the Official Gazette, establish a State Board\textsuperscript{57} for Assisted Reproductive Technology having jurisdiction exercising powers and discharging its functions and duties conferred on it.

The State Boards shall consist a maximum of twelve members, prescribed by the State Government and, unless the rules otherwise provide, the State Boards shall consist of the following members, namely \textsuperscript{58}–

- The Secretary of the Department of Health and Family Welfare, who shall be Chairperson, \textit{ex officio};
- The nominee of an Indian professional society concerned primarily with assisted reproduction who shall be the Vice Chairperson, \textit{ex officio};
- An officer not below the rank of a Joint Secretary, who shall be the Member-Secretary of the Board;
- Up to nine other members – of whom at least four shall be women – who shall be experts in the fields of assisted reproduction, gynaecology, embryology, andrology, bioethics, mammalian reproduction, medical genetics, social science, law, or human rights, to be nominated by the State Government.

The Chairman of the State Board shall nominate a Vice Chairman from among its members\textsuperscript{59}. The meeting of State Board will be held when necessary but not less than thrice a year and at such time and place as the Chairperson of the State Board may deem fit. The Chairperson of the State Board shall preside over the meetings while in his absence Vice Chairperson of the Board shall preside over the meeting\textsuperscript{60}.

3.5.18 Powers and Functions of State Boards\textsuperscript{61} –

The Bill provides that the State Board shall have the responsibility for laying down the policies and plans for assisted reproduction in the State\textsuperscript{62}. It also provides that the State Board, taking into account the recommendations, policies and regulations of the National Board,\textsuperscript{63} may –

\begin{itemize}
  \item \textsuperscript{56} Id section 6
  \item \textsuperscript{57} Id sub-section (1) of section 3
  \item \textsuperscript{58} Id Section 6(2)
  \item \textsuperscript{59} Id Section 6(3)
  \item \textsuperscript{60} Id section 7
  \item \textsuperscript{61} Id section 8
  \item \textsuperscript{62} Id Section 8(1)
  \item \textsuperscript{63} Id Section 8(2)
\end{itemize}
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- Advise the State Government to constitute a Registration Authority or Authorities as required, at least of six experts in assisted reproduction technology or a related field, for the use of assisted reproductive technology in the State;
- Monitor the functioning of the Registration Authority subject, in particular, to the guidelines laid down by the National Advisory Board;
- Coordinate the enforcement and implementation of the policies and guidelines for assisted reproduction;
- Constitute advisory committees consisting of experts in the field of assisted reproduction and related fields at the State or district level, to make recommendations on different aspects of assisted reproduction;
- Perform such other functions prescribed under this Act;

On the basis of a complaint or otherwise the State Board may *suo moto* examine and review any decision of the Registration Authority. Also the State Board has power to give directions or pass orders which are necessary, with reasons to be recorded in writing.

3.5.19 Term of Office, Conditions of Service, etc., of Chairperson and other Members of State Boards

The Bill empowers the appropriate Government to appoint any person as the Chairperson or other member after being satisfied that his/her professional interest shall not affect prejudicially his functions as such member. The tenure of the Chairperson and every other Member is prescribed in the order of appointment, not exceeding five years, by the appropriate government, who shall be eligible for re-appointment. The resignation of a member should be in writing under his / her hand and addressed to the appropriate Government. A vacancy caused by the resignation or removal of the Chairperson or any other member shall be filled by fresh appointment. If a vacancy occurs in the office of the Chairperson due to his/her death, resignation or otherwise, then one of the members to whom the appropriate Government, by notification, has authorizes, shall act as the Chairperson till the date on which a new Chairperson is appointed and takes charge of the office. In the absence of chairperson,
due to illness or any other cause, the Vice Chairperson shall discharge the function of the Chairpersons, till the date on which the Chairperson resumes his duties. The salaries and allowances payable to and the other terms and conditions of service of the Chairperson and other members are previously prescribed and shall not be varied to the disadvantage of Chairperson or any other member after his appointment. The Chairperson and every other member have to make a declaration of fidelity and secrecy, before entering the office in the form set out in the Schedule. The Chairperson is prohibited for a period of three years from the date on which he ceases to hold such office, to hold any appointment or be connected with the management or administration in any company, hospital, clinic, society, trust or other undertaking in relation to which any matter has been the subject matter of consideration before the State Board.

3.5.20 Procedure of State Boards

The bill provides the State Board powers to –

- Regulate the procedure and conduct of the business;
- Delegate its powers or functions to such persons or authorities as prescribed in the rules or regulations made.
- The Bill also gives the State Boards, powers to –
  - Summon and enforce the attendance of any witness and examine him/her on oath;
  - Order the discovery and production of document or other material objects producible as evidence;
  - Receive evidence on affidavit;
  - Requisition of any public record from any court or office;
  - Issue any order for the examination of witnesses;
  - Any other matter which may be prescribed.

3.5.21 Constitution and Functions of the Registration Authority

The State Government shall constitute the Registration Authority within three months on the advice of the State Board. The Registration Authority shall have a full-time Chairman to the level of a Secretary to the State Government, who shall be a recognised expert in assisted reproductive technology or a related field. Other

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69 Id section 10
70 Id section 10(1)
71 Id section 10(2)
72 Id section 11
members of the Registration Authority shall be part-time members, and shall be adequately compensated for their services. Before appointing any member of the Registration Authority, the Government shall satisfy itself that his/her integrity is such that his/her professional interest shall not affect prejudicially his/her functions as a member. The State Government shall provide adequate staff and secretarial assistance and suitable accommodation to the Registration Authority. The Registration Authority shall issue an appropriate letter granting or rejecting registration to an assisted reproductive technology clinic.

3.5.22 Proceedings before State Boards to be Judicial Proceedings

The Bill deems every State Board to be a civil court. When any offence is described in the bill is committed, the State Board may, after recording the facts constituting the offence and the statement of the accused as provided for in the Code of Criminal Procedure, 1973, forward the case to a Magistrate having jurisdiction to try the same, and the Magistrate to whom any such case is forwarded shall proceed with the complaint as if the case has been forwarded to him under the Code of Criminal Procedure, 1973. Every proceeding before a State Board shall be deemed to be a judicial proceeding within the meaning of sections 193 and 228, and for the purposes of section 196 of the Indian Penal Code, and the Board shall be deemed to be a civil court for all the purposes of section 195 and Chapter XXVI of the Code of Criminal Procedure, 1973.

Chapter III make detailed provisions for procedure for registration and complaints.

3.5.23 Registration and Accreditation of Clinics

Under section 3 of the Bill (ART Bill 2010) all assisted reproductive technology clinics are required to register themselves with the Registration Authority. within prescribed period, form and manner. An application for registration by an assisted reproductive technology clinic under sub-section (1) of this section shall contain the particulars of the applicant including all details of techniques and procedures of assisted reproductive technology practiced at such clinic. The State Board may, subject to prescribed terms and conditions, register any assisted reproductive technology clinic on the basis of the techniques and procedures of assisted reproductive technology practiced at such clinic, such as –

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73 Id section 12
74 Section346 of code of criminal procedure
75 Supra note 42, Section 13
infertility treatment, including Intra-Uterine Insemination (IUI), Artificial Insemination with Husband’s semen (AIH), and Artificial Insemination using Donor Semen (AID), involving the use of donated or collected gametes;

- infertility treatment involving the use and creation of embryos outside the human body;

- processing or storage of embryos;

- research.

Assisted reproductive technology clinic performing any of the functions under sub-section (3) of this section, or any other advanced diagnostic, therapeutic or research functions, shall not practice any aspect of such diagnosis, therapy or research without a certificate of accreditation issued by the State Board. The practice of any aspect of assisted reproductive technology in contravention of the provisions of this section shall constitute an offence under this Act. Assisted reproductive technology clinics registered under this Act shall be deemed to have satisfied the provisions of the PC & PNDT Act, 1994 [amended in 2002], and shall not be required to seek a separate registration under the said Act.

3.5.24 Who May Apply for Registration

- The Bill says that assisted reproductive technology clinics, ART banks and research organizations using human embryos, operative on the date of notification of it, shall obtain a temporary registration within six months of the notification of the State Registration Authority by the State Board, and regular registration within 18 months of the above notification. If an assisted reproductive technology clinic that has applied for temporary registration under this clause to the State Registration Authority does not receive the registration or hear from the above Authority within 60 days of the receipt of the application by the authority, the clinic would be deemed to have received the temporary registration.

- Registration is necessary for every assisted reproductive technology clinic, ART bank or research organization using human embryos, other than the ones specified above, practicing any aspect of assisted reproductive technology, or

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76 Id section 14
carrying out any research on or using human embryos, or using any premises for such purposes.

- Any assisted reproductive technology clinic or ART bank or research organisation using human embryos, by whatsoever name called, may apply to the to the Registration Authority for registration
- Every application under sub-section (2) of this section shall be in prescribed form and shall be accompanied by prescribed fee and documents.

3.5.25 Grant of Registration\textsuperscript{77} –

The Registration Authority after being satisfied, grant registration to the applicant for a term of three years with such terms and conditions as it thinks fit. The Bill also requires the Registration Authority to send a report to the State Board, within one month of a registration being granted. The State Board has to maintain record of all registrations applied for and granted under this section. Before registration being granted the Registration Authority or its authorised person or persons, shall inspect the premises of the applicant.

3.5.26 Renewal, Suspension or Revocation of Registration\textsuperscript{78} –

The Bill gives Registration Authority the power to renew a registration on an application with effect from the date of its expiry if it is satisfied that the criteria prescribed in the Schedule continue to be met. The Registration Authority may suspend the operation of a registration and demand the registration holder to produce documents or furnish evidence as may be required if it has reasonable grounds to believe that the terms and conditions of the registration have not been met. The Registration Authority will give the holder of the registration adequate opportunity to be heard before revoking the registration or continuing it. The Registration Authority shall inform the concerned State Board of every assisted reproductive technology clinic in respect of which it has granted, renewed, revoked or denied a registration under this Act within one month of such an action being taken. The Registration Authority shall be deemed to have granted renewal for three years to the applicant if the applicant does not receive a definitive communication from the Registration Authority regarding the renewal application within sixty days of the receipt of the application in the office of the Registration Authority.

\textsuperscript{77} Id section 15
\textsuperscript{78} Id section 16
3.5.27 Registration Authority to Inspect Premises

The Bill also empowers the Registration Authority to inspect, with or without prior notice on a working day during working hours, any premises or call for any document or material while exercising its powers and functions.

3.5.28 Applicability to ART Banks and Research Organizations

The provisions of sections 13 to 16, as relevant, shall apply also to ART banks and research organizations using human embryos.

3.5.29 Appeal to the State Board

Any person aggrieved by the decision of the Registration Authority may prefer an appeal to the State Board within prescribed time, manner and form. On receipt of an appeal, the State Board may, after giving an opportunity of hearing to the appellant, and after making required inquiry, confirm, modify or set aside the decision of the Registration Authority, within three months of the receipt of the appeal.

The ART Bill, prepared by the ICMR, will make it mandatory for all clinics involved in treating infertility through procedures like artificial insemination with husband's semen (AIH) or in-vitro fertilization-embryo transfer (IVF) to get registered in the country's maiden National Registry of ART clinics.

3.6 Regulation of ART Procedures

The general principles of the Ethical guidelines for biomedical research on human subjects states: There is a certain element of risk associated with all ART procedures. It is, therefore, necessary to ascertain the therapeutic and research value of the ART procedure in each case.

3.6.1 Informed Consent:

After duly counseling the couple/oocyte/semen donor, an informed and written consent should be taken from both the spouses as well as the donor, as the case may be.

- They should explained the various risk factors associated with the procedures like the possibility of multiple pregnancies, ectopic gestation, increased rate of

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79 Id section 17
80 Id section 18
81 Id section 19
83 Supra note 6, Chapter viii.
spontaneous abortion, premature births, higher prenatal and infant mortality as well as growth and developmental problems, possible side effects (e.g. of the drug used) and the risks of treatment to the women in simple language and the words which they can understand.

- Non guarantee of the success / failure of the procedure and the need to reduce the number of viable foetuses, in order to ensure the survival of at least two fetuses should also be explained.
- There may be possible disruption of the patient’s domestic life which the treatment may cause;
- They should be informed about the possible deterioration of gametes or embryos associated with storage, and possible pain and discomfort;
- They should also be explained the importance of informing the clinic about the result of the pregnancy in a pre-paid envelope; and
- Also about the advantages and disadvantages of continuing treatment after a certain number of attempts.
- It should be made clear whether embryos that are not used for transfer could or could not be used for research purposes or implanted in another woman’s womb, or “preserved “ for use at a later date or destroyed. Investigators should ensure that participants are informed and consent is taken afresh in writing on the above issues at every stage.
- Consent may be withdrawn at any time before implantation.
- Specific consent must be obtained from couples who have their gametes or embryos frozen, with regard to what should be done with them in case of death, or if any of the parties becomes incapable of varying or revoking her or his consent.
- Investigators should clarify the ownership of the embryos that they belong to the genetic mother or the laboratory. Abortions should never be encouraged for research purposes.
- No ART procedure will be done without the consent of the spouse or partner.
- There is no ethical objection at the moment for IVF or any other related procedure for research or for clinical application.
- The semen bank assumes the responsibility in selection of the suitable donor on following terms:
Complete physical examination of the donor should be done to ascertain the
good health of the donors of semen, oocyte or embryo. The donor should be
healthy with reasonable expectation of good quality eggs or sperms and
preferably with proven fertility record.

The physical characteristic and mental make-up of the donor should match as
closely as possible to that of the spouse of the recipient, especially with
reference to colour of the skin, eyes and hair, height and build, religious and
ethnic background, the educational level and ABO blood type.

Blood group of the proposed donor and donee should be tested with respect to
Rh compatibility.

No person suffering from any sexually transmitted disease (e.g. syphilis,
gonorrhea, chlamydia, herpes, HIV etc.), infectious disease (e.g. hepatitis B
and C, HIV) or genetically transmissible disease should be used as donor.
Sexually transmitted diseases should be ruled out within a week of obtaining
the seminal fluid.

It is essential that donated semen is cryo-preserved and used only after 6
months as this would enable the centre to retest the donor after 6 months for
HIV and eliminate the potential risk of HIV transmission in the ‘window’
period of HIV infection.

Identity of the donor as well as the recipient should be protected from each
other. However, all the records of the donor must be preserved for at least 10
years in order to trace her / him in case of any eventuality and should be
confidential.

Confidentiality of the entire procedure and its outcome is advisable and
therefore, no relative should be accepted as a donor in order to avoid
identification and claims of parenthood and inheritance rights.

Any information about clients and donors must be kept confidential. No
information about the treatment of couples provided under a treatment
agreement may be disclosed to anyone other than the accreditation authority or
persons covered by the license, except with the consent of the person(s) to
whom the information relates, or in a medical emergency concerning the
patient, or a court order. It is this person(s)’ right to decide what information
will be passed on and to whom.
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- Written consent of the donor should be taken towards unrestricted use of sperms or oocytes for ART, as well as an undertaking from him / her that he / she will not attempt to seek the identity of the recipient. In case the donor is married, the written consent of the spouse should be taken, if possible.
- It is also desirable to restrict the use of semen from the same donor to a maximum of 10 pregnancies to avoid the possibility of an incestuous relationship occurring among the offsprings at a later date.
- In case of the oocyte donor, incurring any health problems related to the process of donation, the costs of the subsequent health care should be borne by the potential recipient couple irrespective of whether they receive oocyte donation as planned or not.
- In case of unused surplus/ spare embryos, consent of the concerned couple should be obtained to cryopreserve such embryos for donation to other needy couples. Such embryo donations should be kept anonymous. The ownership rights of such embryos rest with the couple concerned.

3.6.2 Gametes and Embryos:

Respect for embryo can be shown by -

- Accepting limits on what can be done in embryo research;
- Committing to an inter-disciplinary process of peer group review of planned Research; and
- Carrying out an informed consent process for gamete and embryo donors. Further, respect for the embryo’s moral status can be shown by careful regulation of conditions of research, safeguards against commercial exploitation of embryo research, and limiting the time within which research can be done on embryo up to 14 days’ growth i.e. when the primitive streak appears. This restriction is in keeping with the policy in several nations that permit research with embryos. At this time, the development of nervous system begins and the embryo begins to become a distinct individual.

With regard to use of gametes or embryo -

- no woman shall be treated with gametes or embryos derived from gametes of more than one man or woman;
- no ART clinic shall mix semen from two individuals before use;
- no ART clinic shall provide a couple with embryo of desired sex;
- no gametes shall be stored for more than 10 years;
an embryo shall be stored for not more than five years;
- sale, transfer or use outside India is prohibited;
- The donor shall relinquish all parental rights over the child which may be conceived from her or his gamete.

Women have a special position as care givers for children with disabilities. Since the bulk of care falls upon the women, she should make the final decision among reproductive options, without coercion from her partner, her doctor, or the law. The choice is more than the absence of legal prohibition or coercion and should include the economic and social ability to act upon a decision, including disability. There should be a positive right to affordable genetic services, safe abortion and medically indicated care for children with disabilities.

The possibility of human cloning cannot be rejected since sheep and mice have already been cloned. However, since its safety, success, utility and ethical acceptability is not yet established, research on cloning with intent to produce an identical human being, as of today, is prohibited.

3.6.3 Sourcing, Storage, Handling and Record Keeping for Gametes, Embryos and Surrogates:84

The provision for Sourcing of gametes is provided under section 26 of the ART Bill 2010. It says that ART bank has to do the screening of gamete donors and surrogates; the collection, screening and storage of semen; and provision of oocyte donor and surrogates. An ART bank shall operate independently of any assisted reproductive technology clinic. ART banks shall obtain semen from males between twenty one years to forty five years of age, inclusively, and arrange to obtain oocytes from females between twenty one years of age and thirty five years of age, inclusively. All ART banks shall have standard, scientifically established facilities and defined standard operating procedures for all its scientific and technical activities. All ART banks shall cryo-preserve sperm donations for a quarantine period of at least six months before being used and, at the expiry of such period, the ART bank shall not supply the sperm to any assisted reproductive technology clinic unless the sperm donor is tested for such diseases, sexually transmitted or otherwise, as may be prescribed. An ART bank may advertise for gamete donors and surrogates, who may

84 Supra note 24, Chapter 5.
be compensated financially by the bank. An ART bank is limited to supply the sperm of a single donor for use up to seventy five times. A woman may donate oocytes for six times in her life, keeping three-month interval between the oocyte pick-ups. Eggs from one donor can be shared between two recipients only, provided that at least seven oocytes are available for each recipient. The assisted reproductive technology clinic may preserve all unused oocytes for use on the same recipient(s), or give for research to a bonafide organisation. An ART clinic may use one sample of semen supplied by an ART bank only once on only one recipient. An ART bank shall obtain all necessary information in respect of a sperm or oocyte donor or a surrogate, including the name, identity and address of such donor or surrogate, in such manner as may be prescribed, and shall undertake in writing to the donor to keep such information confidential. No ART bank shall divulge the name, identity or address of any sperm or oocyte donor to any person or assisted reproductive technology clinic except in pursuance of an order or decree of a court of competent jurisdiction. Any person or ART bank who divulges the name, identity or address of a sperm donor in contravention of subsections 11 and 12 of this section shall be guilty of an offence under this Act. An ART bank may, for such appropriate fee as may be prescribed, store any semen obtained from a donor for the exclusive use of the wife or partner of the donor.

Section 27 of the ART Bill 2010 makes provisions for storage and handling of gametes and embryos. It provides that the highest possible standards should be followed in the storage and handling of gametes and embryos in respect of their security, and with regard to their recording and identification. No donor gamete shall be stored for a period of more than five years. An embryo may, for such appropriate fee as may be prescribed, be stored for a maximum period of five years and at the end of such period such embryo shall be allowed to perish or donated to an approved research organization for research purposes with the consent of the patients. If during the period of five years, one of the commissioning partners dies, the surviving partner

85 Id section26(6)  
86 Id section26(7)  
87 Id section26(8)  
88 Id section26(9)  
89 Id section26(10)  
90 Id section26(11)  
91 Id section26(12)  
92 Id section26(13)  
93 Id section26(14)
can use the embryo for herself or for her partner, provided an appropriate consent was taken earlier. Provided that where the persons to whom such embryo relates fails to pay the fee, or both the commissioning persons die, the assisted reproductive technology clinic may, subject to such regulations as may be prescribed, destroy the embryo or transfer the embryo to any accredited research organisation under section 18 of this Act.

Under section 28 of the Bill, the ART bank shall keep a record of all the gametes received, stored and supplied, and details of the use of the gametes of each donor. The records shall be maintained for at least ten years, after which the records shall be transferred to a central database of the Department of Health Research, Government of India. Where an ART bank closes before the expiry of the ten year period, the records shall be immediately transferred to the central database of the Department of Health Research, Government of India. If not otherwise ordered by a court of competent jurisdiction, all ART banks shall ensure that all information about clients and donors is kept confidential and that information about gamete donation shall not be disclosed to anyone other than the central database of the Department of Health Research.

Section 29 of the Draft bill 2010 imposes certain restriction on sale of gametes, zygotes and embryos. It says, the sale, transfer or use of gametes, zygotes and embryos, or any part thereof or information related thereto, directly or indirectly to any party outside India is prohibited and shall be deemed to be an offence under this Act except in the case of transfer of own gametes and embryos for personal use with the permission of the National Board. The sale of gametes, except for use by an assisted reproductive technology clinic for treating infertility, and the sale of zygotes and embryos, or of any information related to gametes, zygotes or embryos, within India, is prohibited and shall be deemed to be an offence under this Act.

### 3.6.4 Regulation of Research on Embryos

The Permission of the Department of Health Research for research is mandatory under section 30 of the draft Bill. It says, the sale of any gametes and embryos or their transfer to any country outside India, for research is absolutely prohibited and shall constitute criminal offence under this Act. Research shall only be conducted on such gametes and embryos that have been donated for such purpose.

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94 Id chapter 6.
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No research shall be conducted using embryos except with the permission of the Department of Health Research. Any person or organisation, by whatsoever name called, may apply to the Department of Health Research for registration as a research institution permitted to conduct research on embryos. While granting permission on an application for registration made under sub-section 4 of this section, the Department of Health Research may prescribe, and the applicant shall be bound by such terms and conditions as it thinks fit. The Department of Health Research may, if it has reasonable grounds to believe that any of the terms and conditions prescribed under subsection 5 of this section have not been met, –

- call for the production of such documents or the furnishing of such evidence as may be required;
- inspect, or order any officer authorised in this behalf to inspect, any premises related to the grant of registration;
- suspend the registration of the research institution, after giving all concerned parties adequate opportunity to be heard.

The Department of Health Research may make such regulations as it thinks fit to provide for research on embryos.

Any act or thing done or omitted to be done in contravention of the provisions of this Chapter shall be deemed to be an offence under this Act.

Section 23 of the Draft Bill provides for regulation of research. It says, in exercising its powers under this chapter, the Department of Health Research shall ensure that –

- research will not be conducted on any human embryo unless such research is necessary in public interest;
- research is not conducted on any human embryo created in vitro unless such research is necessary in public interest to acquire further scientific knowledge;
- no research is conducted on any human embryo, other than embryos given for storage to an ART bank under sub-section (3) of section 27, unless full and informed consent in writing is obtained from the persons from whom such embryo was created;
- no advertisement is issued, and no purchase, sale or transfer is made, of any human embryo created in vitro or any part thereof, except in accordance with this Act;
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- no human embryo created *in vitro* is maintained for a period exceeding fourteen days or such other period as recommended by the National Advisory Board;
- no work is done leading to human reproductive cloning;
- other terms and conditions that may be prescribed by the ICMR, are adhered to.
- any assisted reproductive technology clinic or other research institution or person conducting any research in contravention of the provisions of this Act or any rules or regulations prescribed hereunder shall be an offence under this Act\(^95\).

3.7. Rights and Duties of the Parties of ART

3.7.1. Rights and Duties of the Parties of ART under the Ethical Guidelines for Biomedical Research on Human Subjects, 2000:

The specific principal regarding assisted reproductive technology under the Ethical guidelines for Biomedical research on human subjects\(^96\) made provisions about Legitimacy of the Child born through ART, IVF-ET (*in-vitro* fertilisation and embryo-transfer) and Surrogate Motherhood, Preservation, Utilisation and Destruction of Embryos, Spare Embryos, Right of Children / Parents.

3.7.1.1. Legitimacy of the Child Born through ART:

A child born through ART is presumed to be the legitimate child of the couple having been born within the wedlock and with consent of both the spouses with all the attendant rights of parentage, support and inheritance. Sperm/oocyte donor should have no parental right or duties in relation to the child and their anonymity should be protected.

3.7.1.2. IVF-ET (In Vitro Fertilization and Embryo-transfer) and Surrogate Motherhood:

There are no medico-legal problems posed by IVF-ET with egg and sperm of married couple. Donation of either egg or sperm is governed on the same lines as those for Artificial Insemination Donor with the married partner as the natural or biological mother. IVF-ET with donated egg or sperm or womb leasing will create

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\(^{95}\) Id section31(2)  
\(^{96}\) Supra note 6, at 110.
two to three sets of parents, genetic/ biological and natural. Following consensus has emerged universally with respect to surrogate motherhood:

- Surrogacy is an arrangement in which a woman agrees to carry a pregnancy that is genetically unrelated to her and her husband, with the intention to carry it to term and hand over the child to the genetic parents with whom she enters into a contract for surrogacy.
- It should be resorted to only when it is coupled with authorized adoption wherever applicable.
- The intending parents should have a preferential right to adopt the child subject to six week’s postpartum delay for necessary maternal consent.
- Genetic parent’s claim for the custody of the child in its best interest through adoption would be, to establish that the child is theirs through genetic (DNA) fingerprinting, of which the records will be maintained in the clinic,
- Surrogacy should be resorted to only if medically certified as the only solution to infertility or any other medical bar on pregnancy by the intending mother.
- A qualified consultant should supervise to enforce adequate genetic screening.
- Abortion under the Abortion Law on the medical ground should be inviolate right of the surrogate and the genetic parents have no claim over the amounts already paid.
- The contract for surrogacy is legally enforceable. It shall provide for all expenses related to medical management during pregnancy, delivery, and immediate postpartum period till adoption and should be borne by the intending couple. Monetary compensation for agreeing to be the surrogate may also be specified in the agreement.
- Information about the surrogate shall be kept confidential except with the consent of the person whom the information relates to or by court order.
- ART clinics shall not provide surrogate mothers or information on potential surrogate mothers to couples or individuals.

3.7.1.3. Preservation, Utilisation and Destruction of Embryos:

Research is prohibited on embryos of more than 14 days after fertilization excluding the period during which the embryo was frozen with maximum storage period of 10 years and a 5 yearly review of semen and embryo deposits as practiced in other countries eg. U.K.
3.7.1.4. Spare Embryos:

Embryo-splitting may be resorted to in selected cases for overcoming the paucity of suitable embryos during ART in a couple. Child born of cryo-preserved embryos after divorce is deemed to be illegitimate if existing law does not permit it.

3.7.1.5. Right of Children / Parents:

A child born through ART shall be presumed to be the legitimate child of the couple, having been born in wedlock and with the consent of both the spouses. Therefore, the child shall have a legal right to parental support, inheritance, and all other privileges of a child born to couple through sexual intercourse. Children born through use of donor gametes and their social/adopted parent have the right to know the medical or genetic information about the genetic parents that may be relevant to the child’s health. The child’s has a right to seek information on genetic parent(s) or surrogate mother (including a copy of the DNA fingerprint, if available) on reaching 18 years, except for information on the personal identity of the gamete donor or the surrogate mother unless when required in threatening medical conditions. The couple is not obliged to provide the information to the child on their own when she reaches the age of 18, but no attempt must be made by the couple to hide this information from the child.

3.7.2. Rights and Duties of the parties of ART under the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India:

The National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India also made provisions for rights and duties of the persons involved in the ART procedure.

3.7.2.1. Information and Counselling to be given to Patients\textsuperscript{97}

The ICMR Guidelines make detailed provision for information and counselling to be given to patient. Information must be given to couples seeking treatment, on the following points:

- The basis, limitations and possible outcome of the treatment proposed, variations in its effectiveness over time, including the success rates with the recommended treatments obtained in the clinic as well as around the world.

\textsuperscript{97} Supra note 1, para 3.4
(this data should be available as a document with references, and updated every 6 – 12 months).

- The possible side-effects (e.g. of the drug used) and the risks of treatment to the women and the resulting child, including (where relevant) the risks associated with multiple pregnancy.

- The need to reduce the number of viable foetuses, in order to ensure the survival of at least two foetuses.

- Possible disruption of the patient’s domestic life which the treatment may cause.

- The techniques involved, including (where relevant) the possible deterioration of gametes or embryos associated with storage, and possible pain and discomfort.

- The cost (with suitable break-up) to the patient of the treatment proposed and of an alternative treatment, if any (there must be no other “hidden costs”).

- The importance of informing the clinic of the result of the pregnancy in a pre-paid envelope.

- To make the couple aware, if relevant, that a child born through ART has a right to seek information (including a copy of the DNA fingerprint, if available) about his genetic parent/surrogate mother on reaching 18 years, excepting information on the name and address – that is, the individual’s personal identity–of the gamete donor or the surrogate mother. The couple is not obliged to provide the information to which the child has a right, on their own to the child when he/she reaches the age of 18, but no attempt must be made by the couple to hide this information from the child should an occasion arise when this issue becomes important for the child.

- The advantages and disadvantages of continuing treatment after a certain number of attempts.

- Pamphlets (one-page on each technique in all local languages and English) which give clear, precise and honest information about the procedure recommended to be used will help the couple make an informed choice.
3.7.2.2. Rights of a Child Born through various ART Technologies

The ICMR Guidelines says \(^{98}\):

- A child born through ART shall be presumed to be the legitimate child of the couple, having been born in wedlock and with the consent of both the spouses\(^ {99}\). Therefore, the child shall have a legal right to parental support, inheritance, and all other privileges of a child born to a couple through sexual intercourse.

- Children born through the use of donor gametes, and their “adopted” parents shall have a right to available medical or genetic information about the genetic parents that may be relevant to the child’s health\(^{100}\).

- Children born through the use of donor gametes shall not have any right whatsoever to know the identity (such as name, address, parentage, etc.) of their genetic parent(s). A child thus born will, however, be provided all other information (including that mentioned in Section 3.4.8) about the donor as and when desired by the child, when the child becomes an adult. While the couple will not be obliged to provide the above “other” information to the child on their own, no deliberate attempt will be made by the couple or others concerned to hide this information from the child as and when asked for by the child\(^ {101}\).

- In the case of a divorce during the gestation period, if the offspring is of a donor programme – be it sperm or ova – the law of the land as pertaining to a normal conception would apply\(^ {102}\).

3.7.2.3. Legitimacy of the Child Born through ART\(^ {103}\)

Under ICMR Guidelines, A child born through ART shall be presumed to be the legitimate child of the couple, born within wedlock, with consent of both the spouses, and with all the attendant rights of parentage, support and inheritance. Sperm/oocyte donors shall have no parental right or duties in relation to the child, and their anonymity shall be protected except in regard to what is mentioned under item 3.12.3.

\(^{98}\) Id para 3.12  
\(^{99}\) Id para 3.12.1  
\(^{100}\) Id para 3.12.2  
\(^{101}\) Id para 3.12.3  
\(^{102}\) Id para 3.12.4  
\(^{103}\) Id para 3.16.1
3.7.2.4. Adultery in the case of ART\textsuperscript{104}

ART used for married woman with the consent of the husband does not amount to adultery on part of the wife or the donor. AID without the husband’s consent can, however, be a ground for divorce or judicial separation.

3.7.2.5. Consumption of Marriage in case of AIH\textsuperscript{105}

Conception of the wife through AIH does not necessarily amount to consummation of marriage and a decree of nullity may still be granted in favor of the wife on the ground of impotency of the husband or his willful refusal to consummate the marriage. However, such a decree could be excluded on the grounds of approbation.

3.7.2.6. Rights of an Unmarried Woman to AID\textsuperscript{106}

There is no legal bar on an unmarried woman going for AID. A child born to a single woman through AID would be deemed to be legitimate. However, AID should normally be performed only on a married woman and that, too, with the written consent of her husband, as a two-parent family would be always better for the child than a single parent one, and the child’s interests must outweigh all other interests.

3.7.2.7. Posthumous AIH through a Sperm Bank\textsuperscript{107}

Though the Indian Evidence Act, 1872, says that a child born within 280 days after dissolution of marriage (by death or divorce) is a legitimate child since that is considered to be the gestation period, it is pertinent to note that this Act was enacted as far back as 1872 when one could not even visualize ART. The law needs to take note of the scientific advancements since that time. Thus a child born to a woman artificially inseminated with the stored sperms of her deceased husband must be considered to be a legitimate child notwithstanding the existing law of presumptions under our Evidence Act. The law needs to move along with medical advancements and suitably amended so that it does not give rise to dilemma or unwarranted harsh situations.

3.7.3. Rights and Duties of Patients, Donors, Surrogates and Children under Assisted Reproductive Technology Bill 2010 \textsuperscript{108}

3.7.3.1. Rights and Duties of Patients\textsuperscript{109} –
- Assisted reproductive technology shall be available to all persons including single persons, married couples and unmarried couples.
- In case assisted reproductive technology is used by a married or unmarried couple, there must be informed consent from both the parties.
- The parents of a minor child have the right to access information about the donor, other than the name, identity or address of the donor, or the surrogate mother, when and to the extent necessary for the welfare of the child.
- All information about the patients shall be kept confidential and information about assisted reproductive technology procedures done on them shall not be disclosed to anyone other than the central depository of the Department of Health Research, except with the consent of the person or persons to whom the information relates, or by a court order.

3.7.3.2. Rights and Duties of Donors

- All information about the donors shall be kept confidential and information about gamete donation shall not be disclosed to anyone other than the central database of the Department of Health Research, except with the consent of the person or persons to whom the information relates, or by an order of a court of competent jurisdiction.
- The donor shall have the right to decide what information may be passed on and to whom, except in the case of an order of a court of competent jurisdiction.
- A donor shall relinquish all parental rights over the child which may be conceived from his or her gamete.
- No assisted reproductive technology procedure shall be conducted on or in relation to any gamete of a donor under this Act unless such donor has obtained the consent in writing of his or her spouse, if there, to such procedure.
- The identity of the recipient shall not be made known to the donor.

3.7.3.3. Rights and Duties in Relation to Surrogacy

109 Id section 32
110 Id section 33
111 Id section 34
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- Both the couple or individual seeking surrogacy through the use of assisted reproductive technology, and the surrogate mother, shall enter into a surrogacy agreement which shall be legally enforceable.

- All expenses, including those related to insurance if available, of the surrogate related to a pregnancy achieved in furtherance of assisted reproductive technology shall, during the period of pregnancy and after delivery as per medical advice, and till the child is ready to be delivered as per medical advice, to the biological parent or parents, shall be borne by the couple or individual seeking surrogacy.

- The surrogate mother may also receive monetary compensation from the couple or individual, as the case may be, for agreeing to act as such surrogate.

- A surrogate mother shall relinquish all parental rights over the child.

- Woman below twenty one years of age and over thirty five years of age shall not be eligible to act as a surrogate mother under this Act. Provided that a woman shall not be allowed to act as a surrogate for more than five successful live births in her life, including her own children.

- Any woman seeking or agreeing to act as a surrogate mother shall be medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed, and all other communicable diseases which may endanger the health of the child, and must declare in writing that she has not received a blood transfusion or a blood product in the last six months.

- Individuals or couples may obtain the service of a surrogate through an ART bank, which may advertise to seek surrogacy provided that no such advertisement shall contain any details relating to the caste, ethnic identity or descent of any of the parties involved in such surrogacy. No assisted reproductive technology clinic shall advertise to seek surrogacy for its clients.

- A surrogate mother shall, in respect of all medical treatments or procedures in relation to the concerned child, register at the hospital or such medical facility in her own name, clearly declare herself to be a surrogate mother, and provide the name or names and addresses of the person or persons, as the case may be, for whom she is acting as a surrogate, along with a copy of the certificate mentioned in clause 17 below.

- No surrogate mother shall undergo embryo transfer more than three times for the same couple.
The birth certificate issued in respect of a baby born through surrogacy shall bear the name(s) of individual/individuals who commissioned the surrogacy, as parents.

The person or persons who have availed of the services of a surrogate mother shall be legally bound to accept the custody of the child / children irrespective of any abnormality that the child / children may have, and the refusal to do so shall constitute an offence under this Act.

All information about the surrogate shall be kept confidential and information about the surrogacy shall not be disclosed to anyone other than the central database of the Department of Health Research, except by an order of a court of competent jurisdiction.

A surrogate mother shall not act as an oocyte donor for the couple or individual, as the case may be, seeking surrogacy.

No assisted reproductive technology clinic shall provide information on or about surrogate mothers or potential surrogate mothers to any person.

Any assisted reproductive technology clinic acting in contravention of subsection 14 of this section shall be deemed to have committed an offence under this Act.

In the event that the woman intending to be a surrogate is married, the consent of her spouse shall be required before she may act as such surrogate.

A surrogate mother shall be given a certificate by the person or persons who have availed of her services, stating unambiguously that she has acted as a surrogate for them.

A relative, a known person, as well as a person unknown to the couple may act as a surrogate mother for the couple/ individual. In the case of a relative acting as a surrogate, the relative should belong to the same generation as the women desiring the surrogate.

A foreigner or foreign couple not resident in India, or a non-resident Indian individual or couple, seeking surrogacy in India shall appoint a local guardian who will be legally responsible for taking care of the surrogate during and after the pregnancy as per clause 34.2, till the child/children are delivered to the foreigner or foreign couple or the local guardian. Further, the party seeking the surrogacy must ensure and establish to the assisted reproductive technology clinic through proper documentation (a letter from either the
embassy of the Country in India or from the foreign ministry of the Country, clearly and unambiguously stating that (a) the country permits surrogacy, and (b) the child born through surrogacy in India, will be permitted entry in the Country as a biological child of the commissioning couple/individual) that the party would be able to take the child/children born through surrogacy, including where the embryo was a consequence of donation of an oocyte or sperm, outside of India to the country of the party’s origin or residence as the case may be. If the foreign party seeking surrogacy fails to take delivery of the child born to the surrogate mother commissioned by the foreign party, the local guardian shall be legally obliged to take delivery of the child and be free to hand the child over to an adoption agency, if the commissioned party or their legal representative fails to claim the child within one months of the birth of the child. During the transition period, the local guardian shall be responsible for the well-being of the child. In case of adoption or the legal guardian having to bring up the child, the child will be given Indian citizenship.

- A couple or an individual shall not have the service of more than one surrogate at any given time.
- A couple shall not have simultaneous transfer of embryos in the woman and in a surrogate.
- Only Indian citizens shall have a right to act as a surrogate, and no ART bank/ART clinics shall receive or send an Indian for surrogacy abroad.
- Any woman agreeing to act as a surrogate shall be duty-bound not to engage in any act that would harm the foetus during pregnancy and the child after birth, until the time the child is handed over to the designated person(s).

The commissioning parent(s) shall ensure that the surrogate mother and the child she deliver are appropriately insured until the time the child is handed over to the commissioning parent(s) or any other person as per the agreement and till the surrogate mother is free of all health complications arising out of surrogacy.

3.7.3.4. Determination of Status of the Child\textsuperscript{112} –

- A child born to a married couple through the use of assisted reproductive technology shall be presumed to be the legitimate child of the couple, having

\textsuperscript{112} Id section 35
been born in wedlock and with the consent of both spouses, and shall have identical legal rights as a legitimate child born through sexual intercourse.

❖ A child born to an unmarried couple through the use of assisted reproductive technology, with the consent of both the parties, shall be the legitimate child of both parties.

❖ In the case of a single woman the child will be the legitimate child of the woman, and in the case of a single man the child will be the legitimate child of the man.

❖ In case a married or unmarried couple separates or gets divorced, as the case may be, after both parties consented to the assisted reproductive technology treatment but before the child is born, the child shall be the legitimate child of the couple.

❖ A child born to a woman artificially inseminated with the stored sperm of her dead husband shall be considered as the legitimate child of the couple.

❖ If a donated ovum contains ooplasm from another donor ovum, both the donors shall be medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed, and all other communicable diseases which may endanger the health of the child, and the donor of both the ooplasm and the ovum shall relinquish all parental rights in relation to such child.

❖ The birth certificate of a child born through the use of assisted reproductive technology shall contain the name or names of the parent or parents, as the case may be, who sought such use.

❖ If a foreigner or a foreign couple seeks sperm or egg donation, or surrogacy, in India, and a child is born as a consequence, the child, even though born in India, shall not be an Indian citizen.

3.7.3.5. Right of the Child to Information about Donors or Surrogates ¹¹³ –

- A child may, upon reaching the age of 18, ask for any information, excluding personal identification, relating to the donor or surrogate mother.

- The legal guardian of a minor child may apply for any information, excluding personal identification, about his/her genetic parent or parents or surrogate mother when required, and to the extent necessary, for the welfare of the child.

¹¹³ Id section 36
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- Personal identification of the genetic parent or parents or surrogate mother may be released only in cases of life threatening medical conditions which require physical testing or samples of the genetic parent or parents or surrogate mother Provided that such personal identification will not be released without the prior informed consent of the genetic parent or parents or surrogate mother.

3.8. A Critical Analysis of the ART Bill

ART Bill 2010 has been matter of discussion from the time of its framing among people and stakeholders interested in Indian ART and Surrogacy Arena. The Bill has been placed in various forms since 2005 when the guidelines regulating ART treatments including Surrogacy were first published by Indian Council of Medical Research (ICMR). This was the time when countries in the world and India also started realizing that importance of ART Treatments including Surrogacy and the need to regulate them. This was one of the stepping stones and an initiative by government to regulate Surrogacy Treatment and other ART Techniques in India and also to offer them to overseas patients. Since then Indian ART and Surrogacy arena has been a constant rise and India has earned itself a unique distinction as Surrogacy Capital of World.114 With India fast emerging as a hotspot for rent-a-womb phenomenon, the Union health ministry has now finalized the Assisted Reproductive Technologies (ART) Regulation Bill 2010, which has been sent to the law ministry for its approval.115 The Assisted Reproductive Technology Regulation Bill, prepared by the Indian Council of Medical Research (ICMR), will make it mandatory for all clinics involved in treating infertility through procedures like artificial insemination with husband's semen (AIH) or in-vitro fertilization-embryo transfer (IVF) to get registered in the country's maiden National Registry of ART clinics.116

The document lacks clarity at various levels and uses ambiguous language, which makes effective implementation of the Bill very challenging. Moreover, different parts of the Draft Bill contradict each other leaving certain critical questions unanswered. The analysis of the provisions of the Bill can be summarized below:

Firstly, regarding the issue of making payment to the surrogate, Clause 26 (6) of the Draft Bill states that

114 “Update on ART regulation bill (Draft) 2010”, available on http://www.prlog.org/12027899-update-on-art-regulation-bill-draft-2010.html visited on 19/04/2013 at 1:03 PM
115 “Bill seeks to regulate wombs-for-rent”, The Times of India, Jan 27, 2011,
116 “Bill aims to weed out rent-a-womb clinics”, The Times of India, Jul 13, 2012
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“A semen bank may advertise for gamete donors and surrogates, who may be compensated financially by the bank. But according to Clause 34(2) ‘… the surrogate mother may also receive monetary compensation from the couple or individual, as the case may be, for agreeing to act as such surrogate.’

Further, the Form of Contract between the Semen Bank and the Surrogate [Form- R2 (4)] mentions that “…the consideration for the surrogacy is to be paid by the parent(s) and the Bank will not be responsible for any demand by the surrogate in the form of compensation. The Bank shall not be responsible for payment to the surrogate for any other expenses incurred during the surrogacy period.”

It is therefore not clear from this, who is actually compensating the surrogate. Is it the Bank or the couple/individual?\(^{117}\)

Secondly, the Draft Bill is unclear about the venue of the actual oocyte retrieval and screening process – whether it is at the semen bank or the ART clinic. Clause 26 (1) states that “The collection, screening, storage, and handling of gametes shall be done by a semen bank.” However, Clause 20 (1) mentions that “Assisted reproductive technology clinics shall ensure that patients, donors of gametes and surrogate mothers …have been medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child.”

It is not clear where the screening and testing of donors would take place. Also, since the semen banks are not equipped to conduct oocyte retrieval, the Draft Bill does not specify how they would equip themselves for the purpose.\(^{118}\)

According to Clause 20 (10), Surrogacy cannot be considered for “patients for whom it would normally be possible to carry a baby to term”, the agreement for surrogacy (Form J) makes the surrogate declare that she agrees to act as host mother for the couple “who are / is unable (or do not wish to) have a child by any other means.” While on the one hand the Draft Bill makes only those couples eligible for surrogacy who cannot carry a pregnancy to term, on the other, it offers surrogacy as a choice, in case they do not wish to go through pregnancy.

There is ambiguity regarding the minimum age for oocyte donation. Under Clause 26 (3), the minimum age is mentioned as 21 years, but Rule 4.7.1 says that

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\(^{117}\) Comments and Suggestions on the ART (Regulation) Bill and Rules-2008 by Sama Resource Group for Women and Health, New Delhi, 4 December, 2008 at 2.

\(^{118}\) Id p. 3
“Donors should be healthy women in the age group of 18-35 years.” The Draft Bill must specify its stand regarding the age of donors.

Another point of contradiction is in the Form of Application for Registration or Renewal of Registration of Semen Bank [Form- A (1)]. In the declaration, while on the one hand the person applying for registration of the bank needs to declare that the bank will operate independently of any ART clinic, in the very following point, “he/she must undertake to explain the Act and Rules to all employees of the ART clinic in respect of which the registration is sought.” The independence of the semen bank from the ART clinic as envisaged by the Draft Bill comes into question here.119

The Draft Bill appears narrow in its approach by trying to regulate only a specified number of procedures. For example, the Draft Bill mentions procedures of: Artificial Insemination (AIH/AID), Intra Uterine Insemination (IUI-H/ IUI-D), In vitro fertilization and Embryo Transfer (IVF-ET) and associated techniques of, Gamete Intrafallopian Tube Transfer (GIFT) or Tubal Embryo Transfer (TET), Intra Cytoplasmic Sperm Injection (ICSI) and ICSI with MESA/PESA/TESA/TESE, Oocyte donation or Embryo Donation and Cryopreservation of Semen, Embryos, Oocytes and, Ovarian Tissue. However, the clinics also offer facilities of assisted hatching, blastocyst culture and transfer, laser hatching, ovarian drilling, in vitro maturation, etc. PGD by PCR/FISH techniques have also been introduced in some of the IVF clinics. The Draft Bill does not mention any of these procedures in the entire draft. Further, having included a chapter on research on embryos, it is surprising that the Draft Bill does not mention human embryonic stem cell research and the restrictions related to it.120

The Draft Bill in its present form focuses only on IVF clinics and semen banks, but ignores gynaecologists offering infertility ‘treatments’ and IUI procedure. The Draft Bill also does not take into consideration other consultancies, organizations, agents, private agencies and travel agencies involved in promoting IVF / ART techniques, egg donation and surrogacy. Further, the Draft Bill does not adequately dwell on the regulation and monitoring mechanisms for the public hospitals offering these technologies. Government hospitals are increasingly entering the field of ARTs.121

119 Id p. 3
120 Id p. 4
121 Id p. 5
The Draft Bill allows couples to advertise for surrogates without mentioning ‘details relating to the caste, ethnic identity or descent of any of the parties’ and prohibits ART clinics from seeking surrogates for its clients [Clause 34(7)].

However, advertisements for egg donors or surrogates by advertisement agencies, tourism departments, surrogacy agents, women’s magazines, medical tours and travel agencies are not covered in the Draft Bill at all. Advertisements from couples looking for surrogates and women intending to be surrogates can be found regularly in newspapers and magazines. However, the Draft Bill only prohibits the clinics from advertising but does not foresee the establishment of newer enterprises that may undertake such advertising.\(^\text{122}\)

Further, According to Clause 20(4), “Either of the parties seeking assisted reproductive technology treatment or procedures shall been titled to specific information in respect of donor of gametes including, but not restricted to, height, weight, ethnicity, skin colour, educational qualifications, medical history of the donor, provided that the identity, name and address of the donor is not made known.”

Similarly, the couples are entitled to know the ethnicity and educational qualifications of the donor and details like religion, education and monthly income of the donor must be recorded in Form M [Information on Semen Donor (4, 6, 7)].

Form M2 [Information on Surrogate (8, 9)] requires education and occupation of the surrogate and her spouse (if any), religion and monthly income. Moreover, current practices indicate that surrogates and donors are chosen based on their caste, religion, skin colour and attractive physical features.\(^\text{123}\)

Unfortunately, the Draft Bill also supports these trends by asking for the surrogate’s colour of skin, hair, eyes [Form M2 (34, 35, 36)], which is completely pointless since her oocytes would not be used in the procedures. As she only gestates the child, it is unnecessary to record her genetic characteristics. Giving significance to these characteristics is unnecessary since they do not have a bearing on the genetic composition of a person at all. Revealing particular characteristics of the donor to the intended parents and allowing them to choose donors based on those characteristics ushers in a number of debates. They only encourage eugenic tendencies and lead to discrimination against people belonging to particular religions, castes and with low

\(^{122}\) Ibid
\(^{123}\) Id at 6
educational and economic status. These may promote creation of designer babies and can definitely not be allowed through a national legislation.  

Further, The Draft ART Bill states that, “A child born to a married couple through the use of assisted reproductive technology shall be presumed to be the legitimate child of the couple, having been born in wedlock, with the consent of both the spouses, and shall have identical legal rights as a legitimate child born through sexual intercourse” [Clause 35 (1)]

It is unclear as to why there is a separate list of the legitimacy of a child born through ARTs to married, unmarried and single men and women. Moreover, the definition of legitimacy is premised on the assumption that only children born within wedlock are legitimate. Such an assumption is problematic firstly because a child should not be accorded legitimacy based on her/his birth within or outside “wedlock”. This essentially violates the right of a child to live a life of dignity and respect.

The Draft Bill provides for the child to seek information about donors and surrogates on attaining 18 years of age. But at the same time it excludes information regarding personal identification and only in some cases allows disclosing the information with prior consent of the donor(s) or surrogate. Clause 36(1) of the Draft Bill states that “A child may, upon reaching the age of 18, apply for any information, excluding personal identification, relating to his/her genetic parents or surrogate mother.” But, the document does not make it clear where the child needs to apply for getting the information. Since there are many authorities in the Bill; the Semen Banks, the ART clinics and the central database of the ICMR (where the details of the records will be transferred after expiry of 10 years) will keep the records of the donors and the surrogates, it is not clear where the child should apply.

The Draft Bill also lacks the measures taken to ensure the welfare of the children born through ARTs. In fact there is no section in the Draft Bill, which talks about the welfare of the child. The only points mentioned in this regard are those granting legitimacy to the children born though ARTs and the right of the child to have non-identifying information about his/her genetic parents.

The Draft Bill does not adequately emphasize on adoption. Considering the fact that these technologies do not ‘treat’ or cure infertility, and keeping the potential
risks for the mother and child in mind, a responsible legislation regarding infertility and ARTs must encourage adoption. Rather, this Draft Bill mentions adoption only twice in the whole document. It also mentions that “…Further treatment for the unresponsive couples will then consist of counselling and an in-depth investigation, leading to the use of ART – failing which, adoption may be the only alternative…” suggesting that adoption is an option if and when ARTs fail for a particular couple. This clearly demonstrates the endorsement of the desire for a ‘biological’ child or ‘genetic make’ in an official document.127

The provisions regarding oocyte retrieval and donation bring up a number of questions and concerns. According to Clause 26 (9) of the Draft Bill, “If more than fourteen (14) oocytes are retrieved from the donor at one occasion, they shall not be used for more than two recipients thus ensuring that at least seven oocytes are available for each recipient.” Retrieving large number of eggs (like 14), requires hyper stimulating the ovaries by injecting hormonal drugs, which often entails serious medical complications for women. Moreover, the retrieval procedure in itself is highly invasive, and may result in serious damage/harm to the woman undergoing it. Referring to retrieval of such a large number of oocytes only shows the apathy of the Draft Bill towards the women who undergo the procedures and their health.128

The questions that this clause raises include: By what mechanism has the figure 14 been arrived at? How has it been decided that a woman’s oocytes can go to two women and not to any number higher? Does this also mean that if less than 14 oocytes are retrieved then they can only be donated to one recipient because if given to a second recipient, she will receive less than 7? The ART Bill needs to give some explanation on these aspects.129

It also raises deeper concerns regarding the number of cycles that a woman can undergo while donating. Though the number of times for which a woman can donate oocytes has been limited to 6, [Clause 26(8)] that “No woman shall donate oocytes more than six times in her life, with not less than a three months interval between the oocyte pick-ups.”

However, the maximum number of cycles (which may be 6 or more) has not been mentioned. Also the mechanism to record and monitor the number of times a

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127 Ibid.
128 Id at 8
129 Ibid.
woman is making donations has not been mentioned. The three-month interval between the donations stipulated by the Draft Bill is very inadequate. Three months is too early for a woman to start with the hormonal injections again and undergo another oocyte retrieval. This interval should be increased.\(^\text{130}\)

The Draft Bill states that

“A semen bank shall not supply the sperm of a single donor for use more than seventy-five times” [Clause 26(7)]

At the same time it explicitly mentions that one sample of semen can be given to only one recipient

“One sample of semen supplied by a semen bank shall be used by the ART clinic only once on only one recipient”. [Clause 26(10)]

The rationale behind allowing the sperm of a single donor to be used for seventy-five times is not clear and has not been explained in the Bill. Seventy-five is a considerable figure for a single semen donor’s sample to be supplied.

Further, The Draft Bill states that “ARTs carry small risks both to the mother and the offspring” (Rules 6.13) and mentions the risks for women which include multiple gestation, ectopic pregnancy, spontaneous abortion and Ovarian Hyper Stimulation Syndrome (OHSS). Similarly, while the Draft Bill advises a studied recommendation of foetal reduction for multiple gestation, it does not mention the morbid risks of foetal reduction which include: uterine bleeding, developing infection, premature labour and loss of all fetuses. Moreover, the Document states that foetal reduction may be carried out in cases of multiple pregnancy, “...if so instructed by the patient…” [Clause 23(5)], thus once again levying the onus of the procedure on the couple that the Draft Bill itself qualifies as problematic in another section. On the one hand while the Draft Bill enlists ectopic pregnancies as a ‘small risk’, on the other, it contradicts itself by mentioning that the risk of an ectopic pregnancy could be as high as 5%, and that of OHSS could range from .2 – 8%. (Rules 6.13.3)

The document fails to convey the extent to which the drugs used and procedures performed during ARTs may potentially harm the health and well being of the women undergoing the procedures. This lacuna is also reflected through the consent forms where adequate information on the implications on OHSS (Form D,
Consent form to be signed by the couple for IVF and ICSI) are conspicuous in their absence.

The Draft Bill has left a material void in the process of regulation by not specifying the maximum permissible age of women for undergoing ART procedures. There have been cases where women as old as 60 years or above have been made to conceive through ARTs with serious implications to their health. The Draft Bill should specify the maximum age limit for accessing ARTs.

Another important aspect completely missing in the Draft Bill is the number of embryo transfers and oocyte retrievals corresponding with the age of the woman. It states that “…not more than three oocytes should be transferred for GIFT and not more than three embryos for IVF-ET at one sitting, excepting under exceptional circumstances (such as elderly women, poor implantation, advanced endometriosis or poor embryo quality).” (Rules 6.13.1). This may cause problems as it leaves considerable scope to retrieve more eggs and transfer more number of embryos, putting the woman under risk. Moreover, having said that more than 3 embryos may be transferred in cases of older women, the document, on the same page, states that “Abortion rates rise with increasing age of the mother and in multiple pregnancies, especially with three or more fetuses.” (Rules 6.13.3)

As age has considerable bearing on the number of oocytes retrieved and the embryos to be transferred, it is significant that the Draft Bill should take this into consideration.

The importance of counseling for people who opt for ARTs cannot be emphasized enough, provided the counseling is intended to help them make decisions which are truly ‘best’ for them. If counseling is done by the ART clinics’ own counselors, one may never be sure in whose interest the counseling is actually being done – the couple or the clinic. So, there should be provisions to arrange for counselors independent of the ART clinic and the Draft Bill must provide the guidance for accessing such independent counseling agencies. The Draft Bill, while mentioning the educational requirements of a counselor also states that “…A member of the staff of an ART clinic who is not engaged in any of other full-time activity in the clinic can act as counselor.” (Rules 2.4)

Moreover, there are 31 formats (application forms, record sheets, contracts) attached in the end of the Draft Bill, which make up a significant proportion of the document. MOHFW/ICMR’s attempt at trying to streamline each and every aspect of
the procedures is commendable. However, in the Consent Form for Freezing of Embryos (Form G), giving the embryos for research (in case of death) is given as one of the options. There is no separate Consent Form for embryo research in the Draft Bill. In Form J, (Agreement for Surrogacy) the surrogate needs to declare that she and her husband have not had any extra marital relationship in the last six months. Such provisions are not only unreasonable but also pointless as this impinges on the sexual life of a woman who would be a surrogate. The various Consent Forms, specially the agreement on surrogacy, stress on spousal consent. This prerequisite appears unreasonable since it takes away the right of the surrogate over her own body. This should be reconsidered while finalizing the Bill.

Implementing the regulations that the Draft Bill proposes to put in place would be impossible without the maintenance of a sound database. While the Draft Bill mentions a centralized database to be maintained by the ICMR, there is no proposed system to record the number of children born to Indian surrogates being taken out of the country and the number of foreign couples undergoing ART procedures in India. Serious steps need to be taken to incorporate all these cases into a proper recording system. Moreover, a database, if properly maintained will be useful in giving a sex-desegregated data (in terms of male and female) with respect to children born through IVF and surrogacy which is not available till now.

Further, The Bill does not contain any Consent form for the procedure of PGD. Even in the Agreement for Surrogacy (Form J) though there is a provision that the surrogate will not be asked to undergo sex determination test for the child, this does not incorporate PGD, which is conducted on the embryo before it is transferred into the surrogate’s uterus. Also, the Consent Form for IVF and ICSI (Form D, Pg 81) does not mention anything regarding the prohibition of sex-selection during the procedure. The use of PGD should be strictly monitored and it should be made clear that PGD will be available only where there is a significant risk of serious genetic condition being present in the embryo. Though prohibition of sex selection has been mentioned in Clause 25 (5) but the Draft Bill should deal with the issue of sex-selection more specifically.

Though the Bill claims to be liberal by using the phrase married or unmarried couple as eligible for ARTs, it does not include within its ambit people who are not heterosexual. The Bill clearly defines “Unmarried Couple” as a man and a woman, both of marriageable age, living together with mutual consent but without getting
married [Clause 2(w)] and “Couple”, as persons living together and having a sexual relationship that is legal in the country/countries of which they are citizens or they are living in. [Clause 2(e)] In fact, ‘Couple’ has been defined in such a way in the Draft Bill that homosexual couples from other countries (where same sex relations are legal) can avail ART services from India, but not Indian homosexuals. Under Section 377 of the Indian Penal Code (IPC), “carnal intercourse against the order of nature”, non procreative sexual acts are criminalized and this law is used to criminalize homosexuality. Therefore, Indians who openly identify as homosexuals are not eligible. Interestingly, some of the clinics are regularly providing these procedures to gay couples from abroad. As per both the above-mentioned definitions, only heterosexuals, irrespective of their marital status, are eligible to access these technologies in India. Even the Consent Forms require the signatures of husband and wife, and only at some places does the Draft Bill mention signature of the partner and provide ARTs to heterosexual married couple as a single entity.\(^\text{131}\)

The Draft Bill prohibits the surrogate from being the egg donor [Clause 34(13)]. Therefore, in case the oocyte of the intended mother is unviable and she is not able to carry a pregnancy to term, the couple would have to seek an egg donor and a surrogate. This also indicates that the surrogate would have to undergo IVF even when her oocytes are viable and she can bear the child through the much simpler IUI technique. Whether this has been stipulated to prevent the surrogate from being the genetic mother (and hence having a greater right over the child) or to promote the financial interests of the ART clinic is not known.\(^\text{132}\)

The Draft Bill neither prohibits nor explicitly permits single women for acting as surrogates. Though it permits single women for accessing ARTs in general and also makes statements like “In the event that the woman intending to be a surrogate is married, the consent of her spouse shall be required before she may act as such surrogate” [Clause 34(16)] It does not clearly mention its stand. The MOHFW/ICMR must take care of such ambiguities.\(^\text{133}\)

The ART Bill mentions that a relative acting as a surrogate must be from the same generation [Clause 34(18)] while restricting the age of the surrogate from 21 to 45 years [Clause 34(5)]. However, there may be cases when the prospective surrogate,

\(^{131}\) Id at 18
\(^{132}\) Id at 19
\(^{133}\) Ibid
mother-in-law for instance, falls within the permitted age group but does not belong to
the same generation. The Bill must specify which clause should be adhered to in case
the two clash.  

The document does not carry a much-needed elaboration on the money
transactions between the surrogate, the commissioning couple and the semen banks -
a key problem area. Since the thrust of the regulation is to regularize the commercial
angle in the ‘ART industry’, this aspect is conspicuous in its absence. Firstly, there is
no clarity on the role of the semen banks with regard to financially compensating the
surrogate, as has been explained before. Secondly, the Agreement for Surrogacy
(Form J) states that “I have worked out the financial terms and conditions of
surrogacy with the couple in writing” (Pg 92), but does not mention how this would
be carried out. It appears from this statement that the amount will be mutually decided
by the couple and the surrogate. But, considering that the surrogate in most of the
cases is from a poor socio-economic background, her say in deciding the amount
remains questionable. In case the surrogate is not in the capacity to chalk out the
financial details by herself, by whom would this process be facilitated? Since the
semen bank has a role in sourcing the surrogates, this role may be played by them,
which is not a desirable situation either since the semen bank may itself be involved
financially in this agreement.  

The Bill mentions that ‘No woman shall act as a surrogate for more than 3
successful live births’, ([Clause 34(5)] irrespective of the number of earlier
pregnancies although the medical risks of frequent childbirths without adequate
spacing are well known. The health risks associated with higher and frequent IVF
cycles has been adequately emphasized in an earlier section of this critique.
Restricting surrogacies in terms of successful live births is futile if the number of
cycles is not specified. The document allows three successful live births along with
permitting 3 ETs for a particular couple. Therefore the surrogate may legally undergo
9 cycles, which may result in hazardous consequences for her health. Moreover, she
may be donating oocytes and may also have had children of her own. These coupled
with a lack of record keeping and a subsequent failure to trace a woman’s
reproductive history may have hazardous consequences on her mental and physical
(especially reproductive) health. At the very least, the number of pregnancies that a

\footnotesize

134 Id at 20
135 Ibid
woman has already had must be considered while restricting the number of surrogacies.\textsuperscript{136}

Screening for genetic parents/intended couple has not been emphasized adequately. It has been mentioned in the Contract between the Semen Bank and the Surrogate [Form- R (2)] but has not been listed under the roles and responsibilities of the semen bank. Such provisions in a context where it is the economically weak and the socially marginalized who opt for surrogacy clearly reflect the class and power politics in action. When the Draft Bill makes stringent clauses to screen the surrogate, what is the rationale behind not emphasizing the screening the intended parents to ensure the health and well being of the surrogate?\textsuperscript{137}

Clause 34 (19) states that for foreign couples commissioning a surrogacy, a local guardian will be appointed for the surrogate mother. It is highly unacceptable that an adult woman be under the supervision of a guardian, merely because she agrees to carry someone else’s child, who can interfere in her daily life by directing what to do and what not to do. Also, maintenance of the anonymity of the surrogate comes under question with the presence of a local guardian. While the Bill goes as far as appointing a guardian for the surrogate, it makes no effort in ensuring the safety of the child being taken by the commissioning couple out of the country. There has to be some sort of follow up or reporting back by the couple/individual regarding the child.\textsuperscript{138}

According to Clause 35 (7) \textit{The birth certificate of a child born through the use of assisted reproductive technology shall contain the name or names of the parent or parents, as the case may be, who sought such use}. This implies that the name of the couple seeking ART or commissioning the surrogacy will be written on the birth certificate. The MOHFW/ICMR should consider granting a parental status to the surrogate mother. When a woman gives birth to a child, the birth must be officially documented and that women must be the natural parent of the child born to her. This can be followed by a transfer of parenthood to the intended parents, either through adoption or another system devised for the purpose. Thus the birth certificates must have the name of the genetic/gestational surrogate. Moreover, the document repeatedly assumes that the intended parents are the genetic parents in surrogacy

\textsuperscript{136} Id at 21
\textsuperscript{137} Ibid
\textsuperscript{138} Id at 22
cases. For example, Clause 34(10) states that “The birth certificate issued in respect of a baby born through surrogacy shall bear the name(s) of the genetic parents / parent of the baby.” If the genetic parent of a child born through surrogacy is a donor, then would the birth certificate have the name of the donor?\textsuperscript{139}

The bill must ensure that the intended parents understand and agree that the surrogate has a right to physical integrity and bodily autonomy, i.e., she cannot be forced to abort the foetus, go through foetal reduction or be made to follow a certain diet and lifestyle. These decisions are for the surrogate, and no one else, to make. The MTP, 1971 Act guarantees women in India the right to abortion, while international human rights legislation guarantees her physical integrity. However, no sex-selection should be allowed even with the consent of the surrogate. The surrogate’s right to privacy and physical integrity should be acknowledged in the Bill.\textsuperscript{140}

The ICMR guidelines also state that the surrogacy contract is enforceable against both parties. This seems appropriate in a scenario where the contract needs to be invoked to track the intending parents and legally bind them to take custody. However, neither the guidelines nor the proposed Bill ensures the immediate safety and well being of the child due to the absence of any affiliated bodies enshrined with such tasks. Is the criminal justice mechanism to be invoked by framing charges under Section 317, Indian Penal Code or the Juvenile Justice (Care and Protection of Children) Act, 2000 or is a suit for specific performance of the contract the only remedy? It is also unclear as to who is to be charged in such a case – the surrogate or the intending parents or the fertility experts involved in the conception or any other individual. The Bill lacks proper mechanisms to ensure that the commissioning parents are liable in case they refuse to embrace the baby. This flaw is further heightened in cases where parents refuse to accept this child in case of post partum discovery of the physical or mental disability of the child.\textsuperscript{141}

Moreover, in India there is no single uniform law relating to adoption. The Hindu Adoption and Maintenance Act, 1956 read with the Hindu Minority and Guardianship Act, 1956 applies to Hindus, Buddhists, Jains and Sikhs. In 1990 the

\textsuperscript{139} Ibid

\textsuperscript{140} Sama Team, “Assisted Reproductive Technologies: For Whose Benefit?”, \textit{Economic & Political Weekly}, May 2, 2009 vol xlv no 18 at 29


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Central Adoption Resource Agency (CARA) was established by the Union Ministry of Social Justice and Empowerment for regulation adoption within India, and international adoptions of children from India. In 1995 it issued guidelines on adoptions that all registered/licenced adoption agencies are required to follow these guidelines. A Bill for a uniform law governing adoption was introduced in the Lok Sabha in 1980, but it was opposed and eventually lapsed. The legal position is thus very complex, and no general provision can be made to all couple having children by ARTs or surrogacy.

3.9. The Recommendations of the Law Commission of India

India is emerged as a centre for destination for people wishing both to have assisted reproduction and for surrogacy. According to the report of the Law Commission of India “the usual fee for surrogacy is around $25,000 to $30,000 in India which is around 1/3rd of that in developed countries like the USA. This has made India a favourable destination for foreign couples who look for a cost-effective treatment for infertility and a whole branch of medical tourism has flourished on the surrogate practice. ART industry is now a 25,000 crore rupee pot of gold. Anand, a small town in Gujarat, has acquired a distinct reputation as a place for outsourcing commercial surrogacy. It seems that wombs in India are on rent which translates into babies for foreigners and dollars for Indian surrogate mothers.” Therefore a comprehensive legislation defining the rights and responsibilities of contracting parents, surrogate mothers, rights of child, the responsibility of ART clinic is required to prevent the mal practices and to protect the rights of parties. The Law Commission of India has submitted the 228th Report on “Need for Legislation to Regulate Assisted Reproductive Technology Clinics as well as Rights and Obligations of Parties to a Surrogacy”. The following recommendations had been made by the Law Commission of India:

1. Surrogacy arrangement will continue to be governed by contract amongst parties, which will contain all the terms requiring consent of surrogate mother to bear child, agreement of her husband and other family members for the same, medical procedures of artificial insemination, reimbursement of all reasonable expenses for carrying child to full term, willingness to hand over the child born to the commissioning parent(s), etc. But such an arrangement should not be for commercial purposes.

2. A surrogacy arrangement should provide for financial support for surrogate
child in the event of death of the commissioning couple or individual before delivery of the child, or divorce between the intended parents and subsequent willingness of none to take delivery of the child.

3. A surrogacy contract should necessarily take care of life insurance cover for surrogate mother.

4. One of the intended parents should be a donor as well, because the bond of love and affection with a child primarily emanates from biological relationship. Also, the chances of various kinds of child-abuse, which have been noticed in cases of adoptions, will be reduced. In case the intended parent is single, he or she should be a donor to be able to have a surrogate child. Otherwise, adoption is the way to have a child which is resorted to if biological (natural) parents and adoptive parents are different.

5. Legislation itself should recognize a surrogate child to be the legitimate child of the commissioning parent(s) without there being any need for adoption or even declaration of guardian.

6. The birth certificate of the surrogate child should contain the name(s) of the commissioning parent(s) only.

7. Right to privacy of donor as well as surrogate mother should be protected.

8. Sex-selective surrogacy should be prohibited.

9. Cases of abortions should be governed by the Medical Termination of Pregnancy Act 1971 only.

3.10 The new Indian Medical Visa Regulation:-

The new Indian Medical Visa Regulations dated 9 July, 2012 now stipulate that only married men and women with the subsisting marriage for at least two years will be allowed medical visas for surrogacy. The foreigners visiting India for commissioning surrogacy are required to apply for medical visa with the following conditions:

i. The foreign man and woman are duly married and the marriage should have sustained for at least two years.

ii. A letter from embassy of the foreign country in India or the Foreign ministry of the country should be enclosed with the visa application stating clearly that:
   a. the country recognizes surrogacy and
b. the child/children to be born to the commissioning couple through the Indian surrogate mother will be permitted entry into their country as a biological child/children of the couple commissioning surrogacy.

iii. The couple will furnish an undertaking that they would take care of the child/children born through surrogacy.

iv. The treatment should be done only at one of the registered ART clinics recognized by the Indian Council of Medical Research.

v. The couple should produce a duly notarized agreement between the applicant couple and the prospective Indian surrogate mother.

vi. Before the grant of visa, the couple needs to be informed that before leaving India for their return journey, ‘exit’ permission from FRRO/FRO would be required. Before granting the ‘exit’ the FRRO/FRO will see whether the foreign couple is carrying a certificate from the ART clinic concerned regarding the fact that the child/children have been duly taken custody of by the foreigner and that the liabilities towards the Indian surrogate mother have been fully discharged as per the agreement.

vii. Further it may be noted, for drawing up and executing the agreement cited above at (v), the foreign couple can be permitted to visit India on a reconnaissance trip on tourist visa, but no samples may be given to any clinic during such preliminary visit.

viii. If the listed conditions are not fulfilled, the visa application shall be rejected. ¹⁴²

This is now clear that any single parent, gay person or unmarried couples would be ineligible to apply for a medical visa for undertaking surrogacy arrangement in India.

The present Assisted Reproductive Technology (Regulation) Bill, 2010 is yet to finalized into an official regulatory mechanism and is undergoing debate amongst various ministries. The most crucial proposal is to restrict surrogacy in India to “infertile Indian married couples” only and it would not be allowed to foreigners unless he/she is married to an Indian citizen. Non-Resident Indians (NRIs), Persons of Indian Origin (PIOs) and Overseas Citizens of India (OCIs) shall, however, be

eligible. The object sought to be achieved is to prevent exploitation of Indian women who may be tempted to take the risk in the face of financial hardships. While the Ministry of Home Affairs considers gay couples and single foreigners as ineligible to have a child through surrogacy in India, the Ministry of Health and Family welfare along with Women and Child Development ministry have opined that surrogacy should be allowed for everyone without discrimination. The current suggestion on banning foreign unmarried couples and singles from having a child through surrogacy has given rise to two very pertinent contentions. Firstly, it is argued by those against the proposal, that such a bias does not have a sensible or logical basis and there are more number of single parents in countries like the USA than India. Secondly, the judiciary recognises live-in relationships and the draft ART bill allows Indian single and unmarried people to avail this procedure. Such exclusion would hamper future drafting, thus either the restriction should be for Indians and foreigners alike, or have a better justification backing it.

3.11. Conclusion

No doubt, ART comes to rescue of the infertility. It not only provides the treatment to this serious problem but also exhibit an alternative to the natural means of child bearing. With this growing demand of ART, there arise also certain issues in relation to ART. For which the Government showed a serious concern by providing certain guidelines that can govern this huge ART industry. Though, these guidelines are non-binding in nature, to deal with the ambiguities and complexities the Government of India is seriously working on the process of regulating the ART. Recently the ICMR and MOHFW have drafted the ART bill and rules 2010 but there are loop holes and lacunas in the current bill. The law commission has also pointed out the need of law to regulate ART in India. Government of different countries passed laws and policies to regulate this complex area. It is in this context the next chapter deals with the legal regulation in different countries of the world.

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145 Ibid.